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Health-e-Child Integrated Project (IST-2004-027749)

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Summary

The study received favourable opinions of the relevant ethics committees and the regulatory approvals of the competent national or local authority(ies) in the countries in which the research is to be carried out.

A copy of the official approval from the relevant national or local ethics committees has been provided to the European Commission.

The first six months of the Health-e-Child project have been dedicated to the following topics:

- preparation of the study protocol to be submitted to each Local Ethical Committee
- preparation of the parents and patients (when applicable for age) informed consents in which the design, purpose and additional risk (if any) of the study have been described, and the privacy issues related to data management duly explained.

Different protocols were prepared for the three different disciplines. Moreover dedicated informed consent forms for rheumatologic, cardiologic and brain tumour studies were prepared in each Centre taking part in the project, according to different local law and regulation. A strict adherence to National and European legislations as well as to Ethical frameworks that exist in participating hospitals had been requested.

The protocol and informed consents have been prepared taking into account the guidelines already defined in the description of work of Health-e Child project.

The first aspect to take in consideration is that this project is a non interventional study: all data are derived from routine clinical and instrumental exams that are carried out for ill children regularly. No tests, investigations (e.g arthrocentesis), or procedures (e.g. sedation) will be performed unless it is part of the essential diagnostic approach or medical treatment of the patient.

The major objective of Health-e-Child is to gain a comprehensive view of a child's health by vertically integrating biomedical data, information, and knowledge, that spans the entire spectrum from genetic to clinical to epidemiological aspects.

The proposal is very complex and raises an array of ethical issues that need accurate management. They can be grouped into the following ethically-sensitive areas:

- Research on human beings, specifically children.
- The safe extraction, storage, and usage of human biological samples.
- The collection of personal data and its potential distribution, especially genetic information.

For all the previously mentioned topics a standing Ethical and Legal Review Committee has been created to ensure that all tasks and activities planned during the work-plan adhere to the project's ethical framework, National and European legislations. The committee will also discuss and solve any ethical issues which emerged during the preparation of the protocols or raised by the different Local Ethical Committees.

In addition to a commitment to National and European legislation, it is planned that the project and the Ethical Review Committee will follow an ethical framework which will be able to deal with demands that are wider than just usual personal data, biological sample and genetics questions, such as new issues that may come up during the course of the project.

The afore mentioned legal and ethical branches mandate that they must be applied during the entire lifecycle of the project.

In view of the complex issues involved, now that some fundamental agreement among the three hospitals involved in HeC could be reached and approved by the relevant Ethical Committees, the time is ripe for starting, from 2007, to include also independent experts in ethical issues and legal counsellors into the Ethical and Legal Review Committee of the project.

Inflammatory diseases (Juvenile Idiopathic Arthritis) - IGG report

Responsible Prof. Alberto Martini

Gaslini's Local Ethical Board approved the JIA study on the 16th May 2006. Patient enrolment started on June 2006 and to date 27 patients have been enrolled. All parents and children to which the study was proposed accepted willingly and so far (December 2006) no ethical question raised after the illustration of the study.

No particular problems have emerged during the preparation of the protocol and the informed consent forms. The consent of the child, as well as that of the parent(s) or legal guardian, is required when the child's age and maturity make it necessary. For this reason three different informed consent forms were prepared: one for parent(s) or legal guardian, one suitable for the child and one to be used for patients older than 18 years old and/or to utilize if during the course of the study the enrolled patient will become legally able to consent.

In these informed consent forms, besides the design and purpose of the study it is clearly explained that participation is entirely voluntary and the child will receive the same level of care regardless of whether he or she is enrolled in the project. Moreover parents and children may decide at any stage to retract their consent to the project. In this case all information regarding the clinical status of the patient will be removed from our computer records and any residual biological samples will be eliminated.

The objective of the project is to increase the knowledge of disease features and predictors of outcomes in children with JIA by integrating the data of imaging techniques (X-rays, Magnetic Resonance Image and Musculoskeletal Ultrasound) with those obtained with different techniques and approaches (clinical data, laboratory test, genetic investigations and proteomic data on biological fluids).

Because of this, biological samples (blood and, if there is a clinical indication to make an arthrocentesis, synovial fluid) will be collected and stored in a bio bank for rheumatologic diseases located in Gaslini Institute to perform immunologic, genetic and proteomic investigations. In this regard appropriate informed consent has been prepared and approved by the Gaslini Ethical Board, in which the detailed studies we are going to perform and the modalities to guarantee the patients privacy are fully explained.

Recent advances in genetic research, focalised on Juvenile Idiopathic Arthritis, have enabled us to verify how individual variation of genetic code might influence the disease process or the progression and outcome of the disease after its onset.

It should be pointed out that for JIA no susceptibility genes will be investigated in the context of this study and in all cases the project will ensure the highest coherence to existing regulation on the testing of minors.

We are going to test genes potentially involved in the conditioning of the disease course (disease modifying genes). In particular we are interested in studying some genes involved in the process of bone remodelling to verify their possible role in the establishment and progression of structural bone damage.

In this study the results from genetic analysis, will be integrated with radiological, clinical and immunological evaluations to provide a better knowledge on the role of genetic factors in JIA.

So only at the end of this study, through the vertical integration of different data may we improve the significance of the investigated genetic factors.

Patients and parents are informed that the results of the genetic tests we perform during the study can not immediately be used in clinical practices to predict the disease evolution or support therapeutic decision making.

Genetic data distinguish the identity of individuals, and for this reason, all of the concerns and proactive measures to protect the privacy of the patients involved in this study will be assured in accordance with National and Local Regulation.

Samples will be anonymised in order to allow sample and information sharing for research purpose using standardized anonymisation techniques, and demographic and clinical data attached to anonymised samples will be coded with international nomenclature.

Biological samples will be retained in secure locations for the duration of the project and afterward, following the standard practice of the hospital in which they were gathered. In the informed consent forms we ask directly the parents and children (when applicable for age) if they would want us to eliminate any residual biological samples and the relative information after the termination of the project or if they would want us to store the residual biological samples in the biologic biobank located in our Institute, which acts according to all local regulation and recommendations of the European Society of Human Genetics.

In addition, we asked them to express their written consent for the storage and the utilization of any residual sample only for research purposes dealing with children's diseases or within other research projects which had been approved by an independent ethical committee.

The collection of the data for this study does not require procedures (e.g. arthrocentesis, sedation etc) that are not part of the standard care of children with the only exception of the withdrawing of a small amount of extra-blood for immunological, genetic and proteomic analysis at the time of routine venipuncture.

Magnetic Resonance Imaging (MRI) and Musculoskeletal Ultrasonography of the wrist and/or hip will be performed at study entry, and then after one year and, when possible, a two years follow-up. These imaging techniques have been shown to be superior to clinical and radiographic examination in the diagnosis and localization of joint effusion, inflammation and bone damage. Moreover these examinations are also capable of detecting the involvement of the soft tissues surrounding the joint (tendon, ligament etc) which are not investigated with X rays.

The wrist and the hip, are the sites most vulnerable to changes seen on radiographs in patients with JIA. Furthermore, wrist disease has been associated with a more severe course of arthritis and a poorer functional outcome. Hip involvement is another poor prognostic indicator. In patients with hip involvement, hip MRI is a standard routine practice in order to assess the damage of the hip, which is functionally an extremely important joint. Sedation will be performed only for the execution of hip MRIs in patients who are not able to remain motionless during the scans. This procedure is to be considered as a part of the essential medical diagnostic investigations in a patients affected by JIA and clinical hip involvement.

For longer examinations, the potential need for sedation and intravenous administration of contrast material have limited the widespread use of MRI as a standard imaging modality for assessing arthritis in the paediatric population. Nevertheless, since more specific therapies have been developed for treating JIA recently, imaging scales targeted to the identification of early abnormalities are clearly needed.

In children there is still little experience with wrist MRI, a technique that has been extensively studied in adults affected by rheumatoid arthritis, and represents one of the most promising approach for the early detection of damage and for the sensitive assessment of its progression. The sedation to perform wrist MRI could not be considered a standard routine practice in JIA and so we decided that wrist MRI will only be performed on cooperating patients who do not require general anaesthesia.

In our experience a sedation is not required to perform wrist or hip conventional radiography and musculoskeletal ultrasound.

Paediatric heart diseases - IGG report

Responsible: Dr. Giacomo Pongiglione

Gaslini's Local Ethical Board approved cardiologic study on the 29th September 2006. The patient's enrolment started in October 2006 and up till now 25 patients have been enrolled. All parents and children to which the study was proposed accepted willingly and up to now (December 2006) no ethical question were raised after the illustration of the study. Data collection protocols for Paediatric Heart Diseases have been discussed between Clinicians of the three Hospitals, and established with regard to cardiac MRI, echocardiographic investigations, exercise-testing, familial and paraclinical investigations for CMPs (i.e. basic hematological tests, specific laboratory tests etc...) and genetic investigation (proper diagnostic algorithms have been prepared).

Neither X-rays nor the use of sedation will be additionally performed for research purposes. As stated in the study protocol and in the informed consent form the collection of data for this research project does not require procedures that are not part of the standard care of the child both at diagnostic and therapeutic levels for this specific type of heart disease. Therefore, the use of sedation will be taken in consideration in younger or non collaborative patients only in case that the diagnostic or therapeutic procedure is considered fundamental for the routine management of the patient. In conclusion no test, investigation (magnetic resonance imaging, cardiac catheterization...), nor procedures (e.g sedation) will be performed unless it is part of the essential diagnostic approach or medical treatment of the patient.

Reference is made to the informed consent form in which it has been stated that differently collected data and samples may continue to be conserved in the biobank for a prolonged period only after obtaining the patient's or legal guardian's authorization to do so.

If this event happen within the study course, these patients will be asked to give their personal consent.

Brain tumor (Gliomas) - IGG report

Responsible Dr. Maria Luisa Garrè

During the first quarter a protocol integrating objectives, rational, eligibility criteria and methods of investigation for all research components: clinical, imaging and genetic studies, were designed and discussed with a panel of participating investigators and or co-workers (neuroradiologist, neurosurgeon, neuro-oncologist, genetists, molecular biologist, pathologist and biostatistician). Criteria for access to data bank and informed consent were revisited in relation to the specific project and the specific data base of tumour tissues and blood samples was created.

A data base to collect clinical, imaging, follow-up and pathological data was also created containing the most appropriate information allowing to answer in the final steps of the project to the specific questions of correlation between phenotype and genotype.

For gene expression and putative gene studies, the experimental design included of the protocol consisted of strict rules for DNA, RNA extractions and for other technical procedures.

All the above reported work was done in conjunction with the different sub-units of the project (*UO Neurochirurgia, l'UO Anatomia Patologica, la SS di Neuro-Oncologia e l'UO Neuroradiologia dell'Istituto Giannina Gaslini; UO Cattedra di Genetica Medica dell'Ospedale Policlinico S. Orsola Malpighi, Bologna; Dipartimenti di Informatica dell'Università di Genova e della Sezione elaborazione immagini e di biostatistica della Siemens*) through vis à vis meetings, phone conferences and e-mail discussions.

Gaslini's Local Ethical Board approved Gliomas study on 15th November 2006. By end of December 2006, 12 new cases have been enrolled and added to the series of 108 cases already available as retrospective cases with tumour tissue available in the tumour bank for the genetic study. All parents and children to which the study was proposed accepted willingly and up to now (December 2006) no ethical question raised after the illustration of the study. The study does not requiring any further MRI or any other diagnostic procedures that are not already included in a so called optimal standard diagnostic approach to a child with brain tumour. These types of diagnostic procedures are performed with sedation or general anaesthesia only when there isn't a sufficient child's cooperation to guarantee a correct diagnosis.

The project on Gliomas includes for gene expression a large number of cases collected retrospectively plus all the new cases who will be diagnosed prospectively in the first 3 years of the study. All the cases have tumour and peripheral blood samples in the tumour bank at Giannina Gaslini Children's Hospital. The question which was asked is how to proceed for informed consent with the retrospective cases or with dead cases or lost at follow-up.

The following solution was proposed by Maria Luisa Garrè and it was accepted:

- 1) all patients alive will be contacted and the informed consensus achieved before proceeding with the sample analysis;
- 2) for dead cases caused by disease or complications, the tumours samples and blood can be processed without the informed consent provided that the case remains anonymous according to the rules of the European and Italian Societies of Human Genetics;
- 3) for cases lost at follow-up, it will be as for dead cases but it should be documented that at least 3 attempts of contacting the patient or the family have been done by the PI or co-workers;
- 4) tumour samples and peripheral blood samples remaining after the end of the study will be stored into the tissue bank and the bio-bank at Pathology and Neurosurgery laboratories respectively, for further research projects; access to the bank will be according to the rules of Italian Society of Human Genetics and the requests for new studies submitted to a Scientific Committee composed by one Pathologist, one Neurosurgeon and Neuro-Oncologist.

Inflammatory diseases (Juvenile Idiopathic Arthritis) - UCL report

Investigators: Prof. Patricia Woo, Dr. Clarissa Pilkington, Dr. Cathy Owens

The protocols for the the centres were agreed by conference call and email around April-May2006. During that time Dr. Owens (PI Health-e-child project) was dealing with the European office at University College London, to which the Hospital is associated regarding contracting issues.

In the summer the ethics submission for all parts of the Health-e-child project were being prepared.

New consent forms regarding the rheumatology project had to be written afresh for parents, and children under 18 years of age. The submission was made in September for the October local Ethics Committee meeting.

After their meeting in November, a series of questions were sent round regarding parts of the COREC form, as well as request that the consent forms be revised without specifying what was needed. Dr. Owens did not get a satisfactory reply to explain the need to revise the form and so the revised COREC form went back to the committee without the consent forms being changed.

The committee rejected the submission in December on the basis that the consent forms were not revised. Prof Woo then talked to the chair and discovered that they require the adult consent form to be understandable by someone with a reading age of 12 years old.

These were new guidelines which had not been passed onto the investigators. She therefore revised all the forms and the approval for the project was finally granted on December 21st 2006.

In these informed consent forms, the design and purpose of the study is clearly explained, that the participation in the study was entirely voluntary and the child will receive the same level of care regardless of whether he or she is enrolled in the project. Moreover parents and children may decide at any stage to remove their consent to be part of the study. In this case all information regarding the clinical status of the patient will be removed from our computer records and any residual biological samples will be eliminated.

We are conscious of the time delay, and have started recruiting this month (January 2007).

The objective of the project is to increase the knowledge on disease features and on predictors of outcome in children with JIA by integrating the data of imaging techniques (X-rays, Magnetic Resonance Image and Musculoskeletal Ultrasound) with those obtained with different techniques and approaches (clinical data, laboratory test, genetic investigations and proteomic data on biological fluids).

On that account, biological samples (blood and, if there is a clinical indication to make an arthrocentesis, synovial fluid) will be collected and stored to perform immunologic, genetic and proteomic investigations. For these studies, appropriate informed consent have been prepared and approved by UCL/GOSH Ethical Committee, in which the detailed studies we are going to perform and the modalities to guarantee the patients privacy are fully explained.

We are going to test genes potentially involved in the conditioning of the disease course (disease modifying genes). In particular we are interested to study cytokine and related genes involved in the process of inflammation to verify their potential role in the establishment and progression of structural bone damage. In this study the results from genetic analysis, will be integrated with radiological, clinical and immunological evaluations to provide a better knowledge on the role of genetic factor in JIA. So only at the end of this study, through the vertical integration of different data may we improve the significance of the investigated genetic factors.

Patients and parents are informed that the results of genetic test we perform during the study could not immediately be used in clinical practice to predict the disease evolution and support therapeutic decision. Furthermore, the UK data protection laws are applied to the data collected.

Samples will be anonymised in order to allow sample and information sharing between the centres for research purpose using standardised anonymisation techniques, and demographic and clinical data attached to anonymised samples will be coded with international nomenclature.

Biological samples will be retained in secure locations for the duration of the project. In the informed consent form we ask directly the parents and children (when applicable for age) that the samples be gifted to the researcher at GOSH. We asked them to express their written consent to the storage and the utilization of any residual sample only for research purposes dealing with children's disease and within other research projects which have been approved by an independent ethical committee.

Magnetic Resonance Imaging (MRI) and Musculoskeletal Ultrasonography of the wrist and/or hip will be performed at study entry, and then at one year and, when possible, at a two year of follow-up. These imaging techniques have been shown to be superior to clinical and radiographic examination in the diagnosis and localization of joint effusion, inflammation and bone damage. Moreover these examinations are also capable of detecting involvement of the soft tissues surrounding the joint (tendon, ligament, etc.) that are not investigated with X ray.

The wrist and the hip, are the sites most vulnerable to changes seen on radiographs in patients with JIA. Furthermore, wrist disease has been associated with a more severe course of arthritis and a poorer functional outcome. Hip involvement is another poor prognostic indicator. In patients with hip involvement hip MRI is standard routine practice in order to assess the damage of the hip, which is functionally an extremely important joint.

Sedation will be performed only for the execution of hip MRI in patients who are not able to remain motionless during the scans. This procedure is to be considered as a part of the essential medical diagnostic investigations in a patients affected by JIA and clinical hip involvement.

In children there is still little experience with wrist MRI, a technique that has been extensively studied in adults affected by rheumatoid arthritis, and represents one of the most promising approach for the early detection of damage and for the sensitive assessment of its progression. The sedation to perform wrist MRI can not be considered a standard routine practice in JIA and so we decided that wrist MRI will only be performed in cooperating patients who do not require general anaesthesia.

In our experience a sedation is not required to perform wrist or hip conventional radiography and musculoskeletal ultrasound.

Paediatric Heart disease – UCL Report
Institute of Child Health & Great Ormond Street Hospital for Children
Responsible: Dr. Andrew Taylor

The UCL Institute of Children Health & Great Ormond Street Hospital NHS Trust Research Ethics Committee approved the entire study (including the cardiology component) on 21st December 2006. Patient enrolment will commence on the 1st March 2007, though some retrospective recruitment may be possible for 2006, as all the data that is used for the study is acquired as part of our routine clinical investigations.

Data collection protocols for Paediatric Heart Diseases have been discussed between Clinicians of the three Hospitals, and established with regard to cardiovascular MR, echocardiography, exercise-testing, familial and para-clinical investigations (e.g. basic haematological tests, specific laboratory tests etc.). No genetic data will be acquired at ICH/GOSH, as this is not performed as routine analysis and the ability for genetic data assessment outside the UK is not possible.

Neither X-rays nor the use of sedation will be additionally performed for research purposes. As stated in the study protocol and in the informed consent form, the collection of data for this research project does not require procedures that are not part of the standard care of the child both at diagnostic and therapeutic levels, for the specific type of heart disease. Sedation will be used only in younger or non-cooperative patients for diagnostic or therapeutic procedure that are considered fundamental for the routine management of each patient. In conclusion, no test, investigation (e.g. magnetic resonance imaging, cardiac catheterization etc.), nor procedures (e.g. sedation) will be performed unless it is part of the essential diagnostic approach or medical treatment of the patient.

Clinical data acquired from children in the UK is kept for 25 years.

Inflammatory diseases (Juvenile Idiopathic Arthritis) - APHP report

Responsible Dr. Pierre Quartier

The CPP (committee for the protection of patients) approved the Juvenile Idiopathic Arthritis (JIA) part of HeC study in September 2006. The CNIL (national ethical committee) received, in the same month, the information about the trial and in the absence of any comments from this committee within 2 months it is considered that there is no disagreement. The patient's enrolment started on October 2006 and up till now 14 patients have been enrolled. All parents and children to which the study was proposed accepted it without problems and up to now (December 2006) no ethical question raised after the illustration of the study.

No particular problems have emerged during the preparation of the protocol and informed consent forms. The consent of the child, as well as that of the parent(s) or legal representative, is required when the child's age and maturity make this feasible. For this reason two different informed consent forms were prepared: one for parent(s) or legal representative and one suitable for the child.

In these informed consent, in addition to the design and purpose of the study, it is clearly explained that the participation is absolutely voluntary and that the child will receive the same level of care regardless of whether he or she is enrolled or not in the project. Moreover parents and children may decide at any stage to refuse further participation in the study. In this case all information regarding the clinical status of the patient will be removed from our computer records and any residual biological samples will be destroyed.

The objective of the project is to increase the knowledge on disease features and on predictors of outcome in children with JIA by integrating the data of imaging techniques (X-rays, Magnetic Resonance Image and Musculoskeletal Ultrasound) with those obtained with different techniques and approaches (clinical data, laboratory test, genetic investigations and proteomic data on biological fluids).

Because of this, biological samples (blood and, if there is a clinical indication to make an arthrocentesis, synovial fluid) will be collected and stored in a bio bank for rheumatologic diseases located in Necker hospital to perform immunologic,

genetic and proteomic investigations. In this regard appropriate informed consent forms have been prepared and approved by the CCP.

It should be pointed out that in all cases the project will ensure the highest respect of existing regulation for the testing of minors.

We are going to test genes potentially involved in the conditioning of the disease course (disease modifying genes). In particular we are interested to study some genes involved in the process of bone remodelling to verify their possible potential role in the establishment and progression of structural bone damage.

In this study the results from genetic analysis, will be integrated with radiological, clinical and immunological evaluations to provide a better knowledge on the role of genetic factor in JIA.

So only at the end of this study, through the vertical integration of different data we may improve the significance of the investigated genetic factors.

Patients and parents are informed that the results of genetic test we perform during the study, could not immediately be used in clinical practice to predict the disease evolution or support therapeutic decision.

Biological samples will be retained in secure locations for the duration of the project and afterwards, following standard practice of the hospital at which they were gathered. We asked parents of patients or patients, when their age and maturity permits, to express their written consent to the storage and the utilization of any biological sample for only research purposes dealing with children's disease and within other research projects which have been approved by an independent ethical committee.

The collection of the data for this study does not require procedures (e.g arthrocentesis, sedation etc) that are not part of the standard care of children with the only exception of the withdrawing of a small amount of extra-blood for immunological, genetic and proteomic analysis at the time of routine venipuncture.

Magnetic Resonance Imaging (MRI) and Musculoskeletal Ultrasonography of the wrist and/or hip are performed at study entry, and then at one year and, when possible, at a two year of follow-up. The wrist and the hip, are the sites most vulnerable to changes seen on radiographs in patients with JIA. Furthermore, wrist disease has been associated with a more severe course of arthritis and a poorer functional outcome. Hip involvement is another poor prognostic indicator. In patients with hip involvement, hip MRI is standard routine practice in order to assess the damage of the hip, which is functionally an extremely

important joint. Sedation will be performed only for the execution of hip MRI in patients who are not able to remain motionless during the scans. This procedure is to be considered as a part of the essential medical diagnostic investigations in a patients affected by JIA and clinical hip involvement.

In children there is still little experience with wrist MRI, a technique that has been extensively studied in adults affected by rheumatoid arthritis, and represents one of the most promising approach for the early detection of damage and for the sensitive assessment of its progression. The sedation to perform wrist MRI can not be considered a standard routine practice in JIA, so we decided that wrist MRI will be performed only in cooperating patients who do not require general anaesthesia.

In our experience a sedation is not required to perform wrist or hip conventional radiography and musculoskeletal ultrasound.

Paediatric Heart disease - APHP report

Responsible: Dr. Younes Boudjemline

Since the ethical committee approval in September, patients have begun to be enrolled into the study. As the study doesn't change our current medical practices, the cases have been considered an 'observatory'. In situations like this informed consent is not specifically required. But patients can refuse to participate in the study without compromising their follow up meetings. At the end of reporting period we were able to collect data, since the ethical committee had approved the study, but we were not yet authorised to export the data because still waiting for CNIL's formal approval.

We enrolled 10 patients for cardiomyopathy since September 2006 and 4 patients for dilated right ventricle since the November 2006.

No patient or family who was approached about the project refused to take part once the concepts had been illustrated to them.

Currently we are recording medical data in a paper form which is an identical file to the electronic file. Echocardiographic exams were stored on a hard drive as raw data. We have not performed X-rays investigations to date as it was considered of no utility to the specific patients in question.

In very rare cases, management of some patients requires sedation, especially for blood sample. As regards the Health-e-Child protocol, no additional use of sedative medication has taken place. As to genetic investigations, DNA storage remains subject to a more exact definition of all legal ramifications and is undergoing further investigation.