Paediatric ACL Monitoring Initiative (PAMI)  
Frequently asked questions  

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Content

PAMI PROJECT ...................................................................................................................................................................... 1
  What is the aim of the PAMI project? ................................................................................................................................................ 1
  Who is in charge of the PAMI? ....................................................................................................................................................... 1
  Which categories of data are being collected in the PAMI project? .............................................................................................. 1
  How data are being collected in the PAMI project? ..................................................................................................................... 1

PARTICIPATION PROCEDURE AND REQUIREMENTS ............................................................................................................. 2
  Who can participate to the PAMI project? ........................................................................................................................................ 2
  How to participate to the PAMI project and become a partner institution? ................................................................................... 2
  What are the responsibilities of the partner institutions involved in the PAMI project? ..................................................................... 2
  How to choose the principal investigator and local study coordinator? ............................................................................................ 2
  What is included in the PAMI research protocol? .......................................................................................................................... 3
  Which languages are currently available in the PAMI project? ....................................................................................................... 3
  What if my local language is not available? .................................................................................................................................... 3

PAMI WEB PORTAL ............................................................................................................................................................... 4
  How can I access the PAMI database? ............................................................................................................................................. 4
  How is the PAMI web portal presented? ......................................................................................................................................... 4

DATA PROTECTION, QUALITY AND DISSEMINATION ............................................................................................................ 6
  What about data protection? .......................................................................................................................................................... 6
  How are the collected data protected? ........................................................................................................................................... 6
  Will the data be made available to the public? ................................................................................................................................. 6
  Can I use PAMI data? ................................................................................................................................................................... 6
  Is the quality of data controlled? ................................................................................................................................................... 6
  How can an individual patient get access to his/her own data or request his/her data to be deleted? ................................………… 6

PATIENT INFORMATION AND CONSENT ............................................................................................................................... 7
  Do the patients need to provide written informed consent prior to participation? ........................................................................... 7
  What if a patient decides to withdraw their consent to participate in the PAMI project? .............................................................. 7

ASSISTANCE .......................................................................................................................................................................... 7
  What kind of assistance may I expect from the PAMI steering committee? .................................................................................. 7

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PAMI PROJECT

What is the aim of the PAMI project?

The main purpose of the “Paediatric Anterior Cruciate Ligament Monitoring Initiative” (PAMI) is to create a novel pan-European system to collect and analyse data from orthopaedic surgeons who are treating children and adolescents with anterior cruciate ligament (ACL) injury.

This project will provide important insights into the natural history of ACL injured knees in children, and will allow discriminating those patients needing operative treatment from those who benefit most from a nonoperative treatment. Furthermore, large-scale objective outcome data will provide the knowledgebase necessary for a first-time-ever proposal of international treatment guidelines.

Who is in charge of the PAMI?

The PAMI project is initiated, promoted and financially supported by ESSKA (European Society of Sports Traumatology, Knee Surgery & Arthroscopy – www.esska.org). The project is undertaken in collaboration with the Sports Medicine Research Laboratory of the Luxembourg Institute of Health (LIH – www.lih.lu) for its scientific and technical experience regarding the project objectives.

The project is managed by a dedicated steering committee (PAMI steering committee) who guarantees that the general objectives of the PAMI project are met and who is responsible for project related communication and dissemination of results. In May 2020, the management of the project was also placed under the umbrella of the Basic Science Committee of ESSKA.

Which categories of data are being collected in the PAMI project?

Data collected within the PAMI project mainly consist in:

- Patient data: birth date, sex, height, weight, skeletal age
- Injury data: date, injured side, previous knee injuries, activity at time of injury, injury mechanism
- Clinical examination data: Lachman test, pivot shift test, recurvatum
- Treatment data (conservative treatment or surgery): in case, a surgical treatment is chosen, information on skeletal age at the time of the ACL reconstruction as well as ACL and associated surgical procedures
- Follow-up data: yearly questionnaires (International Knee Documentation Committee Subjective Knee Form in Children (Pedi-IKDC); Pediatric Activity Rating Scale (HSS Pedi-FABS)).

How data are being collected in the PAMI project?

All data for the PAMI project are collected from a secured website (PAMI web portal) which access is strictly limited to PAMI partner institutions (participating centers).
PARTICIPATION PROCEDURE AND REQUIREMENTS

Who can participate to the PAMI project?

Any orthopaedic surgeon or medical doctor from a public or private hospital/practice, treating children and adolescents with anterior cruciate ligament (ACL) injury, can participate to the PAMI project and become the principal investigator of his/her institution.

How to participate to the PAMI project and become a partner institution?

1. Request a copy of the “PAMI register regulation” to take notice of the legal and administrative requirements entailed by your participation
2. File a the PAMI participation request form included as an annex of the “PAMI register regulation”, identifying the participating institution, as well as the principal investigator and local study coordinator acting on its behalf
3. The PAMI research protocol including the patient information and the consent forms will be send to you so you can adapt these documents in accordance with your legal requirements and file an application of the complete research protocol with your national or institutional ethics committee
4. Forward a copy of the adapted research protocol as well as the official ethical clearance confirmation to the PAMI steering committee
5. Personal access codes to the PAMI web portal and its user guide will be sent once all the above mentioned administrative steps are fulfilled and your participation has been cleared by the PAMI steering committee.

What are the responsibilities of the partner institutions involved in the PAMI project?

Partner institutions should:

✓ seek ethics clearance to their local or national ethics committee when applicable, in accordance with their national laws and regulations
✓ be responsible for patient recruitment, patient information and collection of written consent for participation and data collection

All PAMI project activities are explained in the document entitled “PAMI register regulation” that can be send to the interested institution upon request. Strict adherence to this regulation by the participating institutions/hospitals is mandatory.

How to choose the principal investigator and local study coordinator?

For legal reasons, the principal investigator (PI) must be a medical doctor employed by the partner institution and treating children and adolescents with anterior cruciate ligament (ACL) injury. The PI assumes the responsibility for proper conduct of the study within the local institution. He/she is responsible for protecting the rights, safety, and welfare of subjects under his/her care during the
study. The local study coordinator will receive the access to the PAMI web portal. The PI can be the local study coordinator or she/he can decide to delegate this task to a colleague.

What is included in the PAMI research protocol?

The PAMI research protocol includes:

- The research protocol in English
- Patient information and consent form for minors and adults in English and local language if available (Word format to allow for modification)
- Case report form in English
- Patient questionnaires in English and local language if available (International Knee Documentation Committee Subjective Knee Form in Children (Pedi-IKDC); Pediatric Activity Rating Scale (HSS Pedi-FABS))

Please contact the PAMI steering committee for any other document that may be requested by the local/national ethics committee and/or institution.

Which languages are currently available in the PAMI project?

The patient information and consent forms as well as the International Knee Documentation Committee Subjective Knee Form in Children (Pedi-IKDC) and Pediatric Activity Rating Scale (HSS Pedi-FABS) are currently available in:

- English
- French
- German
- Norwegian
- Italian

To date, only the International Knee Documentation Committee Subjective Knee Form in Children (Pedi-IKDC) is available in Dutch. The HSS Pedi-FABS will be implemented soon.

What if my local language is not available?

In case your local language is not yet available, we may ask you to help in the translation process. For questionnaires such as the Pedi-IKDC and HSS Pedi-FABS, the procedure to validate new translations will be send to you by the PAMI steering committee. The latest is mandatory before the implementation of the questionnaires within the PAMI web portal.
PAMI WEB PORTAL

How can I access the PAMI database?

Access to the PAMI database is limited to partner institutions (participating centers). Personal access codes will be send to the site coordinator once the center participation has been cleared by the PAMI steering committee.

The system works with a two-factor authentication solution: the site coordinator enters his username/password and receives a numeric code via SMS on his personal cell phone to be able to enter the platform.

How is the PAMI web portal presented?

The PAMI web portal opens with the list of patients integrated by the partner institution. It also allows sending the Pedi-IKDC and HSS Pedi-FABS questionnaires every year via email through a dedicated page name “Reminders”.

2. By clicking on the injury of interest, its detail and treatment are shown.

![Injury details](image)

3. By clicking on the treatment of interest, its detail and data are shown. On this page, the center has the possibility to add/visualize: (1) the clinical examination, (2) the surgical report (in case of a surgical treatment), (3) the Pedi-IKDC and HSS Pedi-FABS questionnaires and their completion status.

![Treatment plans](image)
DATA PROTECTION, QUALITY AND DISSEMINATION

What about data protection?
All collected data are entered into the PAMI database. A declaration to your national data protection agency is not necessary, since the database is located and declared in Luxembourg.

How are the collected data protected?
All data collected within the PAMI database are pseudonymised to ensure maximal data protection and avoid legal issues related to data transfer between different European countries. The local project coordinator has the responsibility of managing a correspondence table between the patient’s personal data and the pseudonymised code generated by the PAMI database, to ensure long-term follow-up of each patient.

Will the data be made available to the public?
Data will be made available to the public only in summarized forms via the yearly report and other dissemination activities outlined in the protocol and the register regulations.

Can I use PAMI data?
Each center can have access to his own data via the local project coordinator’s access to the PAMI webportal. The data recorded within the PAMI database shall be made available to be used for quality-related work and research whenever possible. All requests to access PAMI data shall be addressed to the PAMI steering committee according to the procedures described in the “PAMI register regulation”.

Is the quality of data controlled?
The PAMI steering committee will yearly contact each partner institution to control for patients to be excluded from the database (i.e. wrong inclusion, consent withdrawn) and to indicate any issues in the data (missing data, ...).

How can an individual patient get access to his/her own data or request his/her data to be deleted?
Access to patient own data is provided as per request by the patient to the local project coordinator. Patients can also exert their data access and management rights directly via the data controller.
PATIENT INFORMATION AND CONSENT

Do the patients need to provide written informed consent prior to participation?

Before any patient’s data can be uploaded into the PAMI database, it is the responsibility of the participating institutions/hospitals to inform the patient, obtain an explicit, signed consent form and store them securely to make them available at request by an external auditor. The consent of the patient’s legal representatives and, once the patient has reached the age of majority, the date of his/her own consent will be recorded.

When children or minors are involved in research, both the assent of the child or minor and the permission of his or her parent(s) are usually required. However, legal age, consent process and whether only one or both parents need to sign the consent agreement may vary between countries. In general, consent of one parent is sufficient if the research involves minimal risk. Please make sure that you are in accordance with your national laws and regulations.

What if a patient (or a parent) decides to withdraw the consent to participate in the PAMI project?

In case the patient’s legal representatives or the patient him-/herself decides to withdraw from the study after having provided explicit informed consent, the date of withdrawn consent will be recorded and no further information regarding that patient may be uploaded into the PAMI database as of that date.

ASSISTANCE

What kind of assistance may I expect from the PAMI steering committee?

Any request / suggestion can be forwarded at any time to the PAMI steering committee.

The PAMI steering committee will provide you with the following information:

✔ The “PAMI register regulation” including the PAMI participation request form
✔ The PAMI research protocol including all relevant documents to assist in preparing the ethics application
✔ Your personal access codes to the PAMI web portal and its user guide once your participation has been cleared by the PAMI steering committee

Furthermore, the PAMI steering committee may help you with any issues related to:

✔ The use of the PAMI web portal such as any issue accessing the portal and/or encoding data
✔ The conduct of the study such as the management of your patient list and on-site organization