CLINICAL DETERMINANTS OF DISEASE PROGRESSION IN PATIENTS WITH LIMB GIRDLE MUSCULAR DYSTROPHIES TYPE 2E

Version 1.0, 24/04/2020

INFORMATIVE AND MANIFESTATION Of THE CONSENT
TO THE PROCESSING OF PERSONAL DATA
According to art.13 of GDPR and national privacy law
(Personal data protection law)
Version 1.0, 24/04/2020

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Study promotor: Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano, Via Francesco Sforza n. 28

Processing holder and purpose

Processing holder and reaponsible of data protection

Processing holder and responsible of protection of furnished data for the development of the present study is Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Istituto di Ricovero e Cura a Carattere Scientifico, in Milano, Via Francesco Sforza, 28. Data Protection Officer could be reached out writing an e mail to: dpo@policlinico.mi.it.

Aims of data treatment

The Processing Holder will process your personal data, particularly those about your health and your clinical history and other sensible data, solely depending on the study. Data processing is essential for the developing of the study, any refuse will not permit your participation to it.

Personal data and data suitable to reveal genetical information, provided by you or collected by third authorized part will be processed for the following purposes: pathologies prevention, treatments and therapies of patient's relatives, prevention and treatments programs (trial); genetic diagnosis tests; diagnosis of rare disease; prenatal diagnosis; gene mapping; prevention of genetic disease in at risk population prevention of rare disease included n rare disease national/regional registry biomedical or statistical research; drug trial for clinical use; studies on human genome; organ and tissue transplantation.

Further you consent that sensible data provided could be used for purpose of assisted reproduction; provision of health services by electronic means relating to database or supply of goods, epidemiological survey, revelation of mental, infectious and spreading disease, seropositivity, organ and tissue transplantation and healthcare expenditure monitoring

For this purpose data will be collected by Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Istituto di Ricovero e Cura a Carattere Scientifico and communicated in anonymized form to the Sponsor/Promotor of the study or to people or external society which act on their behalf also in non-European countries and which will be allowed to consult them for the aims described above also for projects in collaboration with private or public society, (at local, national or international level), research societies, scientific institutes, associations, foundations, non-profit associations, laboratory analysis, National Health Service organisms, physicians and paramedical staff, drug companies. Also, the data could be disclosed to person who are in charge for data processing. Data provided will be saved fort the time necessary for the purpose of the handling and then will be deleted unless further requests of the patient to participate in clinical trials. Patient won't be identifiable during registry consultation and his/her personal data will be anonymized. The

identification will be allowed only to the registry administrator and to those in charge to relate directly with the patient according to the processing needs.

Type of data:

Physician who will follow you during the study will guarantee the anonymity by processing your common and sensible data separately from those personal in order to avoid any associating with you, namely anonymizing them. For this purpose, the physician will provide you a code which will identify you all the study long. Your relevant data, except for your name, will be registered, handled and collected together with this code and all the clinical data concerning your health. Only the physician and the authorized person will be able to connect this code to your name.

Modalities of data processing and transmission to third party

Your data will be processed electronically and not electronically and send to the sponsor of the study or, eventually, to third society charged of monitoring and verify the study. Your participation to the study implies that, according to the law on drug clinical trials, the staff of promoter / sponsor center or external societies in charge for this will monitor and verify the study. Further Ethics Committee and Italian or foreign Health Authorities will be allowed to know your data, also those in the original clinical documents, exclusively to control study's proceedings and accuracy and fairness of collected data, adopting in any case all the precautions in order to guarantee the confidentiality of your identity and always in the boundaries of the law, particularly in respect of principles of fairness, competence, accuracy, pertinence and completeness of the processing (art.11 D.Lgs. 196/2003). Data will be released only and strictly in anonymized form, for example in scientific publications, in statistics and congresses.

Rights of the data subject

According to article 77 of GDPR, by addressing directly to Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, con sede legale in Milano, Via Francesco Sforza n. 28, all'attenzione del Titolare del trattamento or to you have the right to obtain:

a) confirmation of the existence or not of your personal data, even if not yet recorded, and their communication in intelligible form.
b) The update, the rectification or, if he or she as interest to, the integration of the data.
c) The cancellation, transformation in anonymous form or the blockage of any data processed unlawfully, including those whose storage is not necessary in relation to the aims for which the data were collected or later processed.
d) A statement that the operations indicated in letters b) and c), including their content, have been made known to those to whom the data have been communicated or released, except in the case of this being found to be impossible or requiring the use of means which are clearly disproportionate to the protected right.

Also, you have the right to completely or partially oppose for legitimate reasons to the processing of your personal data if relevant for the aim of the collection. The data subject can exercise the rights or address any request by contacting. You will be able to end in any time and without any specific reason your participation to the study. In this case any further data concerning you will be collected without a prejudice on using those already provided in order to finalize the research without affecting its results.

Finally, you have the right to claim to Privacy Supervisor– e-mail garante@garanteprivacy.it

The study Promotor

Fondazione IRCCS Ca' Granda

Ospedale Maggiore Policlinico

CONSENT EXPRESSION

Read the above reported informative and understood the whole test, subscribing this I agree to the processing of my personal data and to their relocation out of the European Union for research purpose and within the limits and the modalities described above.

Patient name and surname (block letters): _____

Patient signature (or of the tutor): _____

Date _____

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I, the undersigned, hereby declare that I have correctly and completely informed the patient about the nature, the aims and the modalities of his/her data processing and in good conscience I believe they have been understood. Further I confirm that this consent has been released from the subject voluntary and that this informative will be saved in the base of Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, according to the law and another copy will be handed to the participant to the study.

Physician name and surname (block letters): _____

Physician signature_____

Date _____