

Informed consent
Belgian pilot Spine Registry study

Dear madam, dear sir,

You are about to undergo a surgical intervention in the back or you will soon start a multidisciplinary back rehabilitation treatment. The result of this treatment is important in several ways. First and most important is that the outcome for you is as favorable as possible. However, also for your specialist and for the hospital it is very useful to receive feedback on the choice for and quality of spinal treatments, in order to make adjustments when needed. Finally, for the Spine Society of Belgium¹ and the health authorities, it is crucial to monitor the quality of spinal treatments on a national level in order to guarantee continuous optimal quality of care.

The best way to measure treatment outcomes is by means of a standardized method. For this reason, the Spine Society of Belgium had developed questionnaires that enable objective and quantifiable measurement of pain, disability and quality of life. Prior to your scheduled treatment as well as at 4 predetermined intervals after the treatment (at 3 months, at 6 months, at 1 year and at 2 years) you will be invited to fill out a short questionnaire. The default format is digital. It is possible that you will be contacted in writing or by telephone call to remind you to fill out the questionnaire. In case you do not have access to a computer, tablet or smartphone, you can ask an exception in your hospital to be offered the questionnaires on paper forms.

The data we receive from you through the questionnaires will be supplemented with information on diagnosis and treatment. The latter information will be entered by your treating specialist, who has access to your medical records in the context of your treatment. Further, the data will be coded, sent to and processed in a dedicated database. Your name will not be entered in the database, and your national number will be encoded in order to protect your privacy.

The present study has been approved by the Sectoral Committee, division of Health, of the Privacy Commission, deliberation nr 18/021 of February 20th 2018 and July 3th 2018.

The individual data are only accessible by the researchers of the Spine Society of Belgium, for analyses that are meant to result in reports for the participating specialists and for the health authorities. Finally, the results will also be forwarded to an international database on spinal treatments in the United Kingdom (Spine Tango) for international benchmarking.

By filling out the questionnaires, you implicitly consent to participate in this permanent quality monitoring study. Beware that participation is not compulsory and that not participating will have no effect whatsoever on the quality of care you will receive. However, we still would like to emphasize the societal importance of the current quality project. It is only by measuring that we can safeguard permanent quality of care. We therefore hope we will be able to count on you and sincerely thank you for this.

If you have further questions or would like to obtain additional information on this project, you can contact your treating physician or send an email to info@spinesociety.be.

Yours sincerely,
Your treating physician

Prof. dr. E. Munting Prof. dr. B. Depreitere
On behalf of the Spine Society of Belgium

¹ Overarching scientific society that manages the current project in 16 hospitals in Belgium
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Pilot Spine Registry

This registry was initiated by the Belgian National Health Insurance (RIZIV/INAMI), Tervurenlaan 211, 1150 Brussel. The RIZIV/INAMI is the sponsor and data controller of the registry. This project was, besides the Privacy Commission, also approved by an independent ethical committee (Ethische Commissie Onderzoek UZ/KULeuven, who acts as central ethical commission), after consulting the ethical commissions of the participating hospitals. The registry is carried out according to the guidelines of good clinical practice (ICH/GCP) and according to the most recent version of the 'declaration of Helsinki' which was drafted to protect participants of clinical trials. Under no circumstances, the approval by the ethical committee should be seen as the reason to take part in this registry. Your treating physician in your hospital participates in the project.

Besides filling out the questionnaires, nothing else will be asked from you in the context of this project. Participation in the registry is voluntary. A decision not to participate, to withdraw or to stop filling out the questionnaires will not affect the quality of care delivered, nor will it have any effect on the relationship with your treating physician.

You always have the right to ask the investigators about the type and purpose of the data that are being collected in the registry. You also have the right to consult your personal information and have corrections made in it through the investigators. The data of the registry will be stored for at least 20 years, or at least 30 years in case the data are part of your medical file.

As all other medical data, the data collected in this registry will be treated confidentially and in compliance with medical confidentiality rules, the international guidelines (ICH/GCP) and the Belgian law (according to the legal requirements as provided in the Belgian law of July 30th 2018 on the protection of personal data and the Belgian law of August 22th 2002 on patient rights). When you choose to stop your participation in the registry, no more new data will be collected. The data collected up to that point will still be used for analysis.

Under strict conditions, access to the medical records can be granted to authorised personnel of the sponsor (RIZIV/INAMI) or their representative(s), to regulating authorities or other persons empowered by law to evaluate correct implementation of the registry. Access is only allowed to check the quality of the collected data, and thus not systematically granted. Direct access to the medical records by third parties will only be granted in the presence of and under the responsibility of the treating specialist (or one of his/her colleagues). All people receiving access to the medical records are bound to professional confidentiality.

Conform the Belgian law of May 7th 2004 on experiments on humans, the sponsor (RIZIV/INAMI) is, even without fault, responsible for all damage directly or indirectly caused by the experiment to participants or their legal representatives. Therefore, an insurance of the KUL-UZLeuven was obtained to cover this liability: policy third-party liability experiments n° 2.99.053.700. Any damage caused by participation to the registry will be covered conform the Belgian law of May 7th 2004.

In case you have any more questions on how your personal data are being used, please do not hesitate to contact your specialist. Also the data protection officer of your hospital (email address in the list below) is always at your disposal. Finally, you have the right to file a complaint to the Belgian authorities for data protection against the way your data is being treated (www.dataprotectionauthority.be).

Pilot Spine Registry

Email addresses of data protection officers per hospital

Universitaire Ziekenhuizen Leuven	Leuven	gdpr.research@uzleuven.be
Universitair Ziekenhuis Antwerpen	Antwerpen	gdpr@uza.be
ZNA Middelheim	Antwerpen	dpo@zna.be
ZNA Stuivenberg	Antwerpen	dpo@zna.be
Imelda Ziekenhuis	Bonheiden	dpo@imelda.be
Sint-Jozefkliniek (AZ Rivierenland)	Bornem	filip.goyens@azr.be
Hôpital Erasme ULB	Bruxelles	dpo@erasme.ulb.ac.be
Grand Hôpital de Charleroi	Charleroi	dpo@ghdc.be
AZ Sint Blasius	Dendermonde	privacy@azsintblasius.be
Ziekenhuis Oost-Limburg	Genk	dpo@zol.be
AZ Sint Lucas	Gent	denis.roels@azstlucas.be
Universitair Ziekenhuis Gent	Gent	dpo@uzgent.be
AZ Groeninge	Kortrijk	dpo@azgroeninge.be
Clinique Saint Pierre	Ottignies	gdpr@cspo.be
AZ Delta	Roeselare	dpo@azdelta.be
Centre Hospitaliers de Wallonie picarde	Tournai	dpo@chwapi.be
GZA Sint Augustinus	Wilrijk	dpo@gza.be