

# Ethical protocol for blood sampling from healthy adult volunteers for research on the immune answer towards biotherapeutic drugs in development

<b>Submission date</b> 01/06/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/11/2021	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Nanobodies® are a recently discovered class of proteins, which show great therapeutic and diagnostic potential in diseases such as cancer. They have many advantages over classical biotherapeutics (engineered biological products), but since Nanobodies originate from camelid animals (e.g. camels and alpacas) there is a risk of unwanted side effects, particularly immune system responses, when used in humans. These responses may drastically limit how effective the therapy is, and in certain cases can even be very harmful for the patient. The aim of this study is to investigate the cause of unwanted immune system reactions to Nanobodies. Specifically, this study will examine the non-human (camelid) aspects of the Nanobodies protein, production side-products and formulation to analyse the main steps responsible for inducing an immune response in humans. This will be done by taking blood samples from healthy volunteers, which will then be analysed in the laboratory to isolate specific, highly sensitive cells that are known to be critical in initiating an immune system response.

### Who can participate?

Healthy adults aged 18-65.

### What does the study involve?

All participants are asked to give a blood sample.

### What are the possible benefits and risks of participating?

The results of this study will be used to generate safer and more efficient Nanobodies, resulting in healthier patients and reduced health costs.

### Where is the study run from?

1. Free University of Brussels (Vrije Universiteit Brussel) (Belgium)
2. University Hospital Brussels (Universitair Ziekenhuis Brussel) (Belgium)

When is the study starting and how long is it expected to run for?  
July 2015 to June 2018

Who is funding the study?  
Free University of Brussels (Vrije Universiteit Brussel) (Belgium)

Who is the main contact?  
Dr C Ackaert

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Chloé Ackaert

**ORCID ID**  
<https://orcid.org/0000-0001-9145-2931>

**Contact details**  
VUB, Building E, 8th Floor  
Pleinlaan 2  
Elsene  
Belgium  
1050

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Ethical protocol for blood sampling from healthy adult volunteers for research on risk mitigation of immunogenicity of Nanobodies®

**Study objectives**  
Rationale of the study: to determine immunogenic regions in the sequence of Nanobodies to be able to change these regions to generate more safe and less immunogenic Nanobodies.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethics Committee of the University Hospital Brussels (UZ Brussel), Belgium - submission planned for 05/06/2015.

**Study design**

Single-centre trial

**Primary study design**

Interventional

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Blood sampling from healthy, adult volunteers for isolation of peripheral blood mononuclear cells (PBMCs) for in vitro analysis of the human immune response towards Nanobodies.

**Interventions**

Blood sampling (up to 450 ml). Nothing is administered.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

T cell proliferation and differentiation in vitro as surrogate marker for the in vivo development of anti-drug antibody formation, measured 1-2 weeks after blood sampling.

**Key secondary outcome(s)**

Immunogenic regions of the Nanobodies are identified and mutated, and the resulting new Nanobodies are tested once again for immunogenicity. Measurements are carried out 2.5 years after blood sampling.

**Completion date**

30/06/2018

**Eligibility****Key inclusion criteria**

1. Good general health
2. Aged 18-65

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Key exclusion criteria**

1. Pregnant (in case of doubt, a test will be taken) or envisages a pregnancy in the near future
2. History of significant inconvenience with blood sampling
3. High risk for HIV, HBV or HCV
4. Has received blood or blood products in the last 6 months
5. Has received any therapeutic treatment that influences the immune system
6. Presence of acute or chronic infection or disease
7. Currently taking drugs, except for contraceptives
8. Associated with the current study

**Date of first enrolment**

01/07/2015

**Date of final enrolment**

01/06/2018

**Locations**

**Countries of recruitment**

Belgium

**Study participating centre**

**Free University of Brussels (Vrije Universiteit Brussel)**

Boulevard de la Plaine 2

Elsene

Belgium

1050

**Study participating centre**

**University Hospital Brussels (Universitair Ziekenhuis Brussel)**

Avenue du Laerbeek 101

Jette

Belgium

1090

**Sponsor information**

**Organisation**

Vrije Universiteit Brussel

ROR

<https://ror.org/006e5kg04>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Free University of Brussels (Vrije Universiteit Brussel)

## Results and Publications

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		09/03/2021	18/11/2021	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes