ISRCTN66203697 https://doi.org/10.1186/ISRCTN66203697

In vivo isolation of circulating tumor cells from peripheral blood of patients with breast cancer by using a structured antibody-coated nanodetector

Submission date
02/12/2011

Recruitment status
No longer recruiting

Registration date
11/01/2012

Overall study status
Completed

Last Edited
10/09/2014

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is the most common cancer in women. The goal of our research is the diagnosis and monitoring of patients after treatment, to improve the detection of tumours coming back or spreading to other parts of the body. We want to evaluate the safety and the functionality of a medical device which is able to detect cancer cells in the bloodstream. A thin catheter, also called a nanodetector, is inserted into an arm vein. The nanodetector has a special coating which has the ability to bind cancer cells and thus to estimate the number of circulating tumour cells. This method has the advantage of fishing for tumour cells in a much larger volume than a standard blood sample taken out of the body.

Who can participate?
Female participants aged 18 years or older who have breast cancer and have not had surgery yet.

What does the study involve?
If you take part in the study, first of all, you will be asked to give a small sample of blood. Should you be eligible to participate the nanodetector will be inserted into an arm vein. The procedure of the insertion of the nanodetector is similar to inserting a small tube for blood collection and takes 30 minutes. This is a standard procedure in hospitals and medical practices. All patients in the study will be treated in the same way. Afterward you will be asked again to give a small sample of blood to check if blood values change after the insertion of the nanodetector.

What are the possible benefits and risks of participants?
The procedure is similar to normal blood collection, therefore the risk for the participants is comparable to the risk of a normal blood collection. All insertions of the nanodetector will be carried out by trained physicians.

Where is the study run from?
Wilelkopolskie Cancer Centre, Poznan, Poland.

When is the study starting how long is the expected to run for?
Patients have been enrolled since May 2011, and the study will end in September 2012

Who is funding the study?
GILUPI, Potsdam, Germany.

Who is the main contact?
Stefanie Herold
stefanie.herold@gilupi.com

Contact information

Type(s)
Scientific

Contact name
Dr Dawid Murawa

Contact details
Ul. Garbary 15
Poznan
Poland
61-866
+48 50 548 85 85
dmurawa@op.pl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIP FSMW EpCAM-Brust-P000

Study information

Scientific Title
In vivo isolation of circulating tumor cells from peripheral blood of patients with breast cancer by using a structured antibody-coated nanodetector: an explorative mono-centre non-randomised trial

Study objectives
The aim of this explorative mono-centre trial is the in vivo proof of concept. The compatibility in patients with operable breast cancer after exposure of the nanodetector in the patient vein for 30 minutes will be tested. Besides of that a performance analysis will be carried out. In a second group of patients with operable breast cancer a double application of the nanodetector will be performed to assess the reliability of the nanodetector after positive evaluation of the proof of

concept. In parallel the antibody-based CellSearch® assay will take place to compare the in vivo isolation with the nanodetector with the FDA-approved CellSearch® method.

On 26/04/2013 the anticipated end date was changed from 30/09/2012 to 31/12/2013.

On 15/05/2013 the target number of participants was changed from 82 to 78. This correction was made due to an error in the original application.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Committee on Bioethics at the Medical University, Charles Marcinkowski in Poznan approved the Clinical Investigation Protocol on 08/04/2010 (Uchwala nr 340/10)
The amendment to protocol 04 approved on 07/10/2010 (Uchwala nr 834/10)
The amendment to protocol 05 approved on 02/12/2010 (Uchwala nr 975/10)
The amendment to protocol 06 approved on 12/05/2011(Uchwala nr 416/11)
The amendment to protocol 07 approved on 08/09/2011 (Uchwala nr 763/11)
The amendment to protocol 08 approved on 05/01/2012 (KB 20/12)

Study design
Explorative mono-centre non-randomised trial

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast cancer (stage I-IV)

Interventions
The first group of patients will receive a single application of the nanodetector. After the complete recruitment of this group of patients a second group will be included in the study. In the second group of participants two nanodetectors will be applied under the same conditions. The nanodetector will be inserted pre-operatively. Each nanodetector will be inserted in an arm vein for 30 min. To demonstrate the functionality of the nanodetector circulating tumor cells will be detected by immunocytochemistry. In parallel, a blood sample will be taken from every patient before the application of the nanodetector. This blood sample will be analyzed with the CellSearch® method. At the end the data from these two methods will be compared.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Positive isolation of circulating tumor cells from the peripheral blood of patients with breast cancer by using the nanodetector (proof of concept)
2. Demonstration of good biocompatibility

Secondary outcome measures
1. Assessment of the accuracy of the nanodetector
2. Review of product application procedures
3. Comparision of the results with the CellSearch® method

Overall study start date
12/05/2010

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Subjects suffering from breast cancer (diagnosed), they are qualified for radical operation of the tumor
2. Age ≤ 18 years
3. Results of laboratory tests are in the area that the patient is qualified to perform an operation
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
78

Key exclusion criteria
1. All results of laboratory tests which represent in the opinion of the auditor a risk to the participation of the patient

2. Different types of allergies (including hay fever)
3. Anaphylactic or anaphylactoid reactions
4. Each of the following autoimmune diseases: antiphospholipid syndrome (lupus anticoagulant), goodpasture's syndrome, lupus erythematosus, recurrent polychondritis, rheumatoid arthritis, sarcoidosis, scleroderma, Sjogren's syndrome, anti-neutrophil cytoplasmic antibodies (ANCA)
5. All forms of immune deficiency: X-linked agammaglobulinemia (XLA), severe combined immunodeficiency (SCID), common variable immunodeficiency (CVID), the lack of immunoglobulin A
6. Serological diagnosis: hepatitis A, B and C, human immunodeficiency virus (HIV), herpes simplex virus (HSV), cytomegalovirus (CMV), syphilis (Wassermann positive test), toxoplasmosis, tuberculosis
7. Laboratory abnormalities of patients with a negative performance for the surgery
8. Detectable inflammatory responses

Date of first enrolment
12/05/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Poland

Study participating centre
Ul. Garbary 15
Poznan
Poland
61-866

Sponsor information

Organisation
GILUPI GmbH (Germany)

Sponsor details
Am Mühlenberg 11
Potsdam
Germany
14476
+49 331 5818 4786
barbara.dlugaszewska@gilupi.com

Sponsor type

Industry

Website
http://www.gilupi.com

ROR
https://ror.org/03fs77m09

Funder(s)

Funder type
Industry

Funder Name
GILUPI GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration