Banking somatic stem cells for screening applications.

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Banking somatic stem cells for clients, from discarded umbilical cords or tumors and giving clients the opportunity to use their somatic stem cells for analytical applications.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43433

Source
ToetsingOnline

Brief title
Banking somatic stem cells for screening applications.

Condition

- Other condition

Synonym
Depends on the screeningtest, stem cells and wishes of the client.

Health condition

Onderzochte aandoening is afhankelijk van het screeningsonderzoek, stamcellen en wensen van de client.

Research involving
Human

Sponsors and support

Primary sponsor: Stem Cells Technologies
Source(s) of monetary or material Support: Stem Cells Technologies

Intervention

Keyword: Biobank, Screening applications, Side effects, Stem cells

Outcome measures

Primary outcome

The main study parameter will be drug concentration gradients and viability of

cell cultures, but the endpoints depends on the drug and tissue the client

wants to screen.

Secondary outcome

Depends on the drug and tissue the client wants to screen.

Study description

Background summary

With somatic stem cells cultures one can try to mimic the tissues in the human body, either healthy or diseased, but at a miniature size and outside the body. As an advantage, experiments can be performed without risk to a living human being. In these experiments, test can be performed to identify benefits from a specific drug for the client, or for example are at high risk of specific drug toxicity, it also opens the road towards more personalized and safer use of drugs. For these kind of tests we need somatic stem cells cultures and the easiest way to procure and bank somatic stem cells, is from discarded tumors and umbilical cords.

Study objective

Banking somatic stem cells for clients, from discarded umbilical cords or tumors and giving clients the opportunity to use their somatic stem cells for analytical applications.

Study design

Many years after banking somatic stem cells, screening applications can be performed in which the stem cells undergo some kind of intervention in order to evaluate the impact. The controlled intervention studies will primarily focus on testing pharmaceutical products containing only well-established drugs that are licensed by the Nederlandse College ter Beoordeling van Geneesmiddelen (CBG) or the the european commission. Before somatic stem cells can be used in screening applications they need to be procured, transported, processed and banked.

Procurement
The obstetrician or the oncologist will receive the collection kit. The protocols inside the collection kit give the obstetrician or oncologist clear instructions how to procure the stem cells.

Transport
After somatic stem cells procurement, Stem Cells Technologies will arrange a pick-up from the hospital and delivery to the Laboratory, all within 48 hours.

Processing
In the laboratory the somatic stem cells will be processed for cryogenic storage.

Banking
The stem cells will then be banked for 25 years.

Drug toxicity tests
When clients file for a screening test, the researcher will design a screening application. The researcher has control over the intervention, its timing, and dose or intensity. In its simplest form, an experimental study to test the effect of a treatment will follow these steps:

- The researcher formally states the hypothesis to be tested
- The researcher selects the banked specimen eligible for the treatment
- The sample is divided into two groups
- One group (the experimental, or intervention group) is given the intervention while the other (the control group) is not
- Outcomes of interest are recorded over time and the results compared between the two groups

The conclusion will be send to the doctor with recommendations for a specific drug for the client

Study burden and risks

All clients need to enrol and answer a questionnaire.
After delivery or before the operation, one blood samples of 10ml will be taken for serology testing.

After delivery or operation the stem cells will be procured outside the body and client should not feel any discomfort.

Contacts

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Stem Cells Technologies

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Stem Cells Technologies

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years or older and mentally competent

Exclusion criteria

Clients infected with HIV, Hepatitis B, Hepatitis C and Syphilis.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-06-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL56324.101.16