Bone Marrow collection in Healthy volunteers

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52489

Source
ToetsingOnline

Brief title
Bone Marrow collection in Healthy volunteers (iCELL2)

Condition

- Spinal cord and nerve root disorders

Synonym
Spinal cord injury; Amyotrophic Lateral Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Neuroplast BV
Source(s) of monetary or material Support: Dit onderzoek wordt betaald door Neuroplast BV

Intervention

Keyword: Bone marrow, collection, HSC, MSC, stem cells

Outcome measures

Primary outcome

Not applicable. Materials are only used for vivo and vitro testing to determine

sterility and to validate the manufacturing.

Secondary outcome

Not applicable

Study description

Background summary

Stem cells are able to modify neuro-inflammation induced by a traumatic event of the central nervous system (traumatic spinal cord injury and/or traumatic brain injury) or by neurodegenerative processes accompanying diseases such as for example Amyotrophic Lateral Scleroses (ALS). Without intervention these diseases cause collateral damage of neural tissue , which can be decreased by the paracrine and immune modulating capabilities of stem cells. Intervention with stem cells in an acute spinal cord injury can decrease the secondary inflammatory cascades and can Improve locomotor functioning and can improve the autonomic functioning of the Central Nervous System needed for better breathing, bowel and bladder control.
In case of ALS stem cells can slow down the disease progression resulting in a better quality of life and an increased life expectancy of the patient.
Preclinical evidence is present and confirmed that this can be achieved by stem cells. However, efficacy has to be confirmed in a randomised and placebo controlled clinical trial with patients. At the moment Neuroplast BV has completed its complete preclinical program, proof and concept studies and regulatory preclinical safety inclusive.

Study objective

Neuroplast has scheduled to start in 2018 with a phase I and a phase II/III clinical trial with patients with a traumatic spinal cord injury to confirm the efficacy and safety in humans. A GMP license to produce clinical grade Neuro-Cells is mandatory for these scheduled studies. To maintain the GMP

status during the year, Neuroplast has to perform sterility testings, validation tests including in-proces controlling and comprehensive characterisation and shelf life testing of the end product Neuro-Cells. With the gathered information Neuroplast is able to compile an IMPD and IB regarding its product Neuro-Cells. Especially for the phase II/III multicenter study, shelf life and transport conditions for respectively bone marrow and respectively Neuro-Cells has to be defined and confirmed. The phase II study is ongoing with the centers located in Copenhagen, and Toledo. The phase I study was executed in Toledo Spain and safety was established successfully. Several tests needs to be validated before the Phase III is allowed to start.

Study design

This study is written to collect bone marrow from healthy volunteers needed to produce Neuro-Cells. The produced Neuro-Cells are only used for vitro and vivo testing, for sterility testing and comparison, for characterisation and shelf life testing and for validation and in proces controlesof the manufacturing. None of these products will be used to give back to patients. Characterisation shall be performed by Flowcytometry and the sterility determine with the use of rapid tests shall be compared with the use of PCR multitest to detect foreign bacteria DNA. Shelf life and optimal storage conditions testing are needed regarding the safe transportation to the European centers Copenhagen and Toledo.

Study burden and risks

The total time burden is estimated at 120 minutes. The risk accompanying blood sampling and bone marrow collection is very low. Bone marrow collection is a routine and standardised medical procedure. Experience during the years 2016 to 2022 with 58 volunteers (iCELL1 and iCELL2) confirmed the safety of the procedure. No volunteer needed extra medical attention. All the volunteers were able to perform all there daily activities without hinder and complaints.
The risk of determining the serology status is that a volunteer may get a positive result which could have consequences for the individual volunteer. In this study the medical investigator is able to act and shall take care to help in coaching and informing the GP.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Men in the age range of 18-50 years and/or women in the age range of 18-50 years;
Written informed consent;
Healthy as concluded by the answers given to questions in a short health questionnaire;
Willing to undergo blood serology testing for HIV, Hepatitis B and C and TPHA (this is a mandatory requirement for accepting Bone marrow under GMP conditions);

Exclusion criteria

Pregnancy
Volunteers who are unable to comply with the rules of this project. Important is if the volunteer cannot follow the schedule of the appointments.
Abuse of alcohol, medicines or illicit drugs.
Legally protected people

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2018
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-07-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	07-10-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-01-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL64917.096.18