Bone Marrow Collection in Healthy Volunteers

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The objective of this project is to collect fresh human bone marrow and to process this bone marrow to an intended product in a short time to enable the use of this product in the acute phase of a disease/disorder/lesion of the central nervous...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system infections and inflammations
Study type	Observational non invasive

Summary

ID

NL-OMON44780

Source
ToetsingOnline

Brief title
Bone Marrow Collection in Healthy Volunteers (iCell)

Condition

- Central nervous system infections and inflammations

Synonym
Spinal Cord Injury / Paraplegic

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Dit onderzoek wordt betaald door Neuroplast BV (Amarna Stem Cells BV wijzigde in maart 2016 zijn naam in Neuroplast BV),Neuroplast BV

Intervention

Keyword: Bone Marrow, Collection, Preclinical, Stam cells

Outcome measures

Primary outcome

not relevant

Secondary outcome

not relevant

Study description

Background summary

Stem cells are able to replace damaged cells and to modulate inflammatory processes and prevent dying of these cells. Traumatic Spinal cord injury is a lifelong disabling disease and patients with a spinal cord injury needs permanent nursing and support and their life expectancy is impaired. Patients with a traumatic spinal cord injury are in general young and up to date no treatment exists.
In literature it is mentioned that bone marrow derived stem cells are pluripotent meaning that they can differentiate in all kind of cell-types and thereby have the potential capability of replacing damaged cells.
Stem cells can divide in progenitor cells and can modulate inflammation by producing factors which can stimulate of inhibit inflammation. Depending on the environment, stem cells can also produce neurotrophic factors which can prevent damaged cells from dying. The mechanism of these trophic factors is mainly offering neuroprotection and preventing apoptosis.
The use of patients own bone marrow derived stem cells (autologous cells) have the advantages that these cells are not rejected and are expected to be safe.
This research is focussed to determine the safety and to establish proof of concept of human derived stem cells administered intrathecally into the cerebrospinal fluid. Finally the samples are also used to characterize the intended product extensively.
These activities are needed before formally a human experiments can be started. These studies are needed for filing in the end for a human clinical trial.

Study objective

The objective of this project is to collect fresh human bone marrow and to

process this bone marrow to an intended product in a short time to enable the use of this product in the acute phase of a disease/disorder/lesion of the central nervous system. the mode of action is supposed to offer protection to damaged neurons and thereby decreasing the disability and to improve neurological outcome.

This project is needed to prepare a human double blind randomized placebo controlled clinical trial with the intended product in patients with a chronic spinal cord injury.

This project needs the fresh bone marrow derived stem cells to establish the following:
a. Install and adjust the manufacturing process and to define release criteria
b. to define the ranges and to characterize the content of the intended product extensively
c. to establish proof of concept in an acute and in a chronic animal model with a compression spinal cord injury
d. to perform the regulatory preclinical safety studies including tumoigenicity, toxicity and biodistribution based on intrathecal administration.

Study design

This project is no intervention. The purpose is to collect from healthy volunteers bone marrow for processing and performing preclinical studies. The intended product is not used in this phase to treat humans. The project collects vital information to obtain approval for a clinical trial. Without this no clinical trial can be applied.

Study burden and risks

A bone marrow collection for diagnostics and for treatment is a standard accepted and safe procedure. The procedure itself is performed at one site of the iliac crest under locally applied anesthetics. During the collection it is possible to experience some temporary discomfort especially during the filling of the first tube. After the collection, the volunteer may experience dolor at the site of the puncture an this can persists for several hours. Sometimes this discomfort is experienced during walking and bicycling. In rare occasions this discomfort may last for several days and the use of pain medication is indicated. In theory there is a small chance of contamination with skin microbes. The use of skilled and trained physicians with the special defined SOP prevents this as much as possible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age range 21-30 years
Written informed consent
Healthy and no contraindication for bone marrow collection

Exclusion criteria

Pregnancy or lactation period
Volunteers who are unable to comply with the rules of this project
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:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2015
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	29-03-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT02118740
CCMO	NL44976.068.13