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A study on cord blood stem cells and platelet-rich plasma for treating pregnancy stretch marks

Submission date
01/11/2021

Recruitment status
No longer recruiting

Registration date
09/11/2021

Overall study status
Completed

Last Edited
05/11/2021

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims:
Pregnancy stretch marks (striae gravidarum) are very common among pregnant women and may cause emotional and psychological stress. Current treatments, however, are not satisfactory. As cord blood-derived platelet-rich plasma (PRP) gel and stem cells have good regenerative capabilities, many studies have found the combination works well in cosmetic applications. The aim of this study is to test the effectiveness of PRP stem cell therapy at treating pregnancy stretch marks.

Who can participate?
Pregnant women aged 23 to 30 who have pregnancy stretch marks

What does the study involve?
Participants have their cord blood collected when giving birth. The collected blood provides the PRP and stem cells used later. The left abdomen of each participant receives no treatment. The right abdomen of each participant is treated with PRP stem cell injections on day 1, day 10, and day 20 after giving birth. The research staff will take photos of the abdomen to see how well the treatment works as time progresses.

What are the possible benefits and risks of participating?
The possible benefits include a safe and effective treatment of the stretch marks and tolerance for cell therapy. The risks involve the body reacting badly to the transplantation (it is not very probable since the materials used are from one’s own body).

Where is the study run from?
Shenyang Maternal and Child Care Service Center, Shenyang, Liaoning (China)

When is the study starting and how long is it expected to run for?
October 2021 to June 2023

Who is funding the study?
Shenyang Engineering Technology R&D Center of Cell Therapy Co., Ltd. (China)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of autologous umbilical cord blood stem cells and platelet-rich plasma on striae gravidarum

Acronym
PRPPSM

Study objectives
The combination of cord blood-derived autologous platelet-rich plasma (PRP) gel and stem cells is effective in treating striae gravidarum.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 29/10/2021, Institutional Review Board of the Shenyang Maternal and Child Care Service Center (No.41 Shenzhou Rd, Heping District, Shenyang, China; +86 (024)86906168; 775104436@qq.com), ref: 2021-001-01

Study design
Single-center non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Striae gravidarum

Interventions
Control group: left abdomen of each participant, no treatment.
Intervention group: right abdomen of each participant, PRP stem cell transplantation.

Transplantation: 1×10^7 autologous cord blood stem cells and 15 ml autologous PRP gel, administered via subcutaneous injection at the site of the striae gravidarum. Three transplantations are planned at Day 1, 10, and 20 post-delivery.

Additional procedures:
1. Before the injection:
Apply lidocaine cream at the injection site beforehand to reduce pain caused by the puncture
2. During and immediately after the injection:
1. Apply manual pressure at the injection area for an extended period to reduce bleeding
2. Apply cold compress at the injection area to prevent bruise
3. In case of a bruise, at 48 h post-transplantation:
Apply hot compress at the bruised area to facilitate absorption

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome(s)
Visual changes measured using abdomen photos at baseline, the 7th day after each transplantation (i.e., day 8, 17, and 27 post-delivery), month 2, and month 3 post-delivery

Key secondary outcome(s))
Measured at baseline, day 8, 17, 27, month 2, and month 3 post-delivery:
1. Pain caused by striae gravidarum measured using self-reporting questionnaires
2. Pruritus caused by striae gravidarum measured using self-reporting questionnaires

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Pregnant women with striae gravidarum
2. Full-term or cesarean delivery
3. Aged 23 to 30 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Participant in other ongoing clinical trials
2. Tested positive for hepatitis B, hepatitis C, HIV, syphilis, EBV, or CMV
3. History of severe allergic reactions or adverse reactions to medication

Date of first enrolment
15/11/2021

Date of final enrolment
14/11/2022

Locations

Countries of recruitment
China

Study participating centre
Shenyang Maternal and Child Care Service Center
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Sponsor information

Organisation
Shenyang Maternal and Child Care Service Center

Organisation
Shenyang Engineering Technology R&D Center of Cell Therapy Co., Ltd

Funder(s)

Funder type
Industry

Funder Name
Shenyang Engineering Technology R&D Center of Cell Therapy Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date