

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/11/2021	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

1. Dr Ning Pei

775104436@qq.com

2. Prof. Yanqiu Yu

yqyu@cmu.edu.cn

3. Dr Jing Li

820367546@qq.com

Contact information

Type(s)

Scientific

Contact name

Dr Ning Pei

Contact details

No.41 Shenzhou Rd

Heping District

Shenyang

China

110004

+86 (0)24 13066597504

775104436@qq.com

Type(s)

Scientific

Contact name

Prof Yanqiu Yu

Contact details

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

A10,400-8 wisdom Second Street

Hunnan District

Shenyang

China

110004

+86 (0)24 13386887215

yqyu@cmu.edu.cn

Type(s)

Public

Contact name

Ms Yutong Ge

Contact details

Shenyang Engineering Technology R&D Center of Cell Therapy Co., Ltd
A10,400-8 wisdom Second Street
Hunnan District
Shenyang
China
110004
+86 (0)24 15142525031
yutong@sycellcenter.com

Type(s)

Scientific

Contact name

Dr Jing Li

Contact details

No.41 Shenzhou Rd, Heping District
Shenyang
China
110004
+86 (0)24 13998160669
820367546@qq.com

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2021

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

Age group

Adult

Sex

Female

Target number of participants

10

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**

No.41 Shenzhou Rd

Heping District

Shenyang

China

110004

Sponsor information

Organisation

Shenyang Maternal and Child Care Service Center

Sponsor details

No.41 Shenzhou Rd

Heping District

Shenyang

China

110004

+86 (0)2486906168

syfykj2011@163.com

Sponsor type

Hospital/treatment centre

Website

<http://sysfybjy.net/index.php?g=&m=Index&a=index>

Organisation

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

Sponsor details

A10, 400-8 wisdom Second Street

Hunnan District

Shenyang

China

110004

+86 (0)15142525031

shenyangcell@163.com

Sponsor type

Industry

Website

<http://www.sycellcenter.com/index.php/cn/Index/index.html>

Funder(s)**Funder type**

Industry

Funder Name

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

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2022

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