

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study on potential of platelet-rich plasma Gel and regular dressing in duration of wound healing in patients who underwent pilonidal sinus surgery

Protocol summary

Summary

The aim of this study was to investigate the influence of platelet- rich plasma (PRP) Gel therapy on wound healing in patients with pilonidal sinus after surgery. One hundred twenty three patients who had surgery for pilonidal sinus were enrolled in this single center phase III clinical trial. All patients were treated by wide excision and open secondary intention. Exclusion criteria were as follows: lower platelet count of $<1000/\mu\text{L}$, hemoglobin $<10\text{ mg/dL}$, anti-proliferative therapies such as chemotherapy and also radiation in past 3 months, anti-inflammation medications in past 2 weeks, growth factor therapies in last 2 weeks, history of diabetes, history of mal-absorption (celiac disease) and any contra-indication in peripheral venues access. After assessment of eligibility criteria, patients were randomized into control and PRP treatment groups using block method. In PRP group, the obtained PRP was additionally injected into the depth (13mm) of the wound. It was also applied to center of each circle (0.1cc) and wound site (1 cm in diameter) through injection. PRP Gel was then added to the 2ml/cm³ of wound volume and the casual dressing was performed. Classical dressing (sterile absorbent cotton gauze) was applied for the control group. In both groups, the wounds were washed by normal saline (0.9%) twice a day. Wound debridement was also performed to remove the necrotic tissues if necessary. Quality of life and healing duration were evaluated in both groups up to the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020418842N11**
Registration date: **2016-03-16, 1394/12/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-16, 1394/12/26

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on potential of platelet-rich plasma Gel and regular dressing in duration of wound healing in patients who underwent pilonidal sinus surgery

Public title

The effectiveness of PRP Gel in wound healing caused by resection of Pilonidal sinus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Any patient diagnosed with pilonidal sinus disease with a scheduled surgery. Exclusion criteria: lower platelet count of $<103/\mu\text{L}$; hemoglobin $<10\text{ mg/dl}$; anti-proliferative therapies such as chemotherapy and also radiation in past 3 months; anti-inflammation medications in past 2 weeks; growth factor therapies in last 2 weeks, history of diabetes, history of mal-absorption (celiac disease); any contra-indication in peripheral venous access ; not willing to participate in the study.

Age

From **18 years** old to **47 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hematology, Oncology and Stem Cell Transplantation Research Center, Tehran Unive

Street address

Shariat Hospital, North Kargar St.

City

Tehran

Postal code

1411713135

Approval date

2015-12-24, 1394/10/03

Ethics committee reference number

ir.tums.horcsct.rec.1394.103.4

Health conditions studied

1

Description of health condition studied

Pilonidal Sinus Disease with abscess

ICD-10 code

L05.02

ICD-10 code description

Pilonidal sinus with abscess

Primary outcomes

1

Description

wound healing time

Timepoint

Weekly up to full healing

Method of measurement

Wound volume measurement by filling the wound with saline. The volume dispensed from the syringe equals the wound volume.

2

Description

Quality of life

Timepoint

Weekly after start treatment up to average 8 weeks

Method of measurement

Quality of life questionnaire SF12 and 26

Secondary outcomes

1

Description

Angiogenesis

Timepoint

In PRP group: between 4-6 weeks In control group: between 8-10 weeks

Method of measurement

Immuno Histochemistry (IHC) on biopsy sample

Intervention groups

1

Description

In intervention group, the obtained PRP was additionally injected into the depth (13mm) of the wound. It was also applied to center of each circle (0.1cc) and wound site (1 cm in diameter) through injection. The injection was performed right after surgery and then weekly. Then the PRP Gel (activated by CaCl_2) was added 2ml/cm³ of wound volume and the casual dressing performed. Washing the wound with normal saline (0.9%) twice a day was ordered. Wound debridement was also performed to remove the necrotic tissues if necessary.

Category

2**Description**

Classical dressing (sterile absorbent cotton gauze) was applied for the control group. Washing the wound with normal saline (0.9%) twice a day was ordered. Wound debridement was also done in order to remove the necrotic tissues whenever necessary.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of general surgery of Shariati Hospital, Tehran University of Medical Sciences.

Full name of responsible person

Shirzad Nasiri

Street address

Clinic of general surgery, Shariati Hospital, North Kargar St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences.

Full name of responsible person

Dr Masoud Younesian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Hematology, Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sci

Full name of responsible person

Kamran Alimoghadam

Position

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PhD

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty