

Lidocaine patch application in painful surgical scars

Submission date 08/11/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/11/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/12/2022	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chronic (long-term) pain after surgery is a frequent complaint in orthopedic practice. Drug and non-drug treatments have been proposed for this condition. Recently, a lidocaine (local anesthetic) patch has been developed. The aim of this study is to test this plaster as a method of treatment for pain after orthopedic surgery in comparison to therapeutic massage performed on the incision.

Who can participate?

Patients between 13 and 70 years old who underwent foot and ankle surgery and experience pain at least 3 months later

What does the study involve?

Patients are randomly allocated to one of two groups. One group apply the lidocaine patch for 12 hours a day for 3 months. The other group perform manual manoeuvres over the scar for 10 minutes each, 3 times a day, over 3 months. Pain, satisfaction with the surgery and quality of life are assessed at the start of treatment and after 30, 60 and 90 days.

What are the possible benefits and risks of participating?

Participants could benefit from pain relief and improved quality of life. The risks include drug hypersensitivity and overdose.

Where is the study run from?

Hospital Ipiranga (Brazil)

When is the study starting and how long is it expected to run for?

December 2016 to September 2017

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Joao Paulo Gonçalves dos Santos
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

64900217.0.0000.5488

Study information

Scientific Title

Lidocaine 5% patch application in painful surgical scars: a randomised controlled trial

Study objectives

The lidocaine 5% patch is a useful tool for relieving post-operative pain in patients who underwent foot and ankle surgeries.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics in Research Committee at Hospital Ipiranga - State Secretary of Health in São Paulo State, Brazil, 08/03/2017, ref: 1.953.666

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Post-operative pain

Interventions

Patients are randomised using random.org to either:

1. Application of lidocaine 5% patch for 12 hours/day for 3 months
2. Manual maneuvers over the scar for 10 minutes each, 3 times a day, over 3 months

Intervention Type

Procedure/Surgery

Primary outcome measure

Pain, measured with the visual analogue scale (VAS) at baseline and 30, 60 and 90 days of follow-up

Secondary outcome measures

Measured at baseline and 30, 60 and 90 days of follow-up:

1. Satisfaction with surgery, measured with the personal satisfaction index
2. Quality of life, measured with the SF-36 questionnaire

Overall study start date

01/12/2016

Completion date

22/09/2017

Eligibility**Key inclusion criteria**

1. Patients between 13 and 70 years old
2. Underwent foot and ankle surgery at Hospital Ipiranga between January 2015 and February 2017
3. Sustained post-operative pain at least 3 months after the procedure

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

50

Total final enrolment

37

Key exclusion criteria

1. Patients younger than 13 and older than 70 years old
2. Allergics to lidocaine
3. Skin lesions or illness
4. Non-union or malunion
5. Infection
6. Patients who abandon follow-up

Date of first enrolment

01/04/2017

Date of final enrolment

30/06/2017

Locations**Countries of recruitment**

Brazil

Study participating centre**Hospital Ipiranga**

Avenida Nazaré, 28 - Ipiranga

São Paulo

Brazil

04262-000

Sponsor information

Organisation

Hospital Ipiranga

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Publication in Acta Ortopedica Brasileira, a Brazilian orthopedic journal.

Intention to publish date

01/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from João Paulo Gonçalves dos Santos (jpgdsantos@gmail.com) or Rafael da Rocha Macedo (rrochamacedo@yahoo.com.br).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/10/2021	01/12/2022	Yes	No