

# Lidocaine patch application in painful surgical scars

<b>Submission date</b> 08/11/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/12/2022	<b>Condition category</b> 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  
jpgdsantos@gmail.com

## Contact information

### Type(s)

Public

### Contact name

Mr Joao Paulo Goncalves dos Santos

### ORCID ID

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### Contact details

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Investigator initiated and funded

# Results and Publications

## 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?
<a href="#">Results article</a>		28/10/2021	01/12/2022	Yes	No