

# Assessment of the effect of phenytoin on cutaneous healing

<b>Submission date</b> 18/10/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/12/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/12/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Assessment of the effect of phenytoin on cutaneous healing from excision of melanocytic nevi on the face and on the back: a single centre prospective non-randomised clinical trial

**Study objectives**

The central hypothesis of this study is that the topical use of phenytoin in cream base accelerates re-epithelialisation of the wound, after surgery of skin lesions, with less healing time and better cosmetic results compared with the use of the cream base alone, for 7, 14, 21 and 60 days post-operatively.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics committee of the Federal University of São Paulo approved on the 16th March 2007 (ref: CEP 0138/07)

### **Study design**

Single centre prospective interventional non-randomised controlled clinical study

### **Primary study design**

Interventional

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

Treatment

### **Health condition(s) or problem(s) studied**

Melanocytic naevi

### **Interventions**

The nevi injuries located on the face and on the back were excised with either 6 or 8 mm modified punches, in accordance with the nevus diameter, creating a superficial cutaneous wound, of the same diameter and depth in the same patient. Used for healing was a phenytoin topical cream 0.5% and cream control. One of the injuries was cared with a wound dressing with phenytoin and the other with cream (control). The dressing was replaced once a day, until the complete healing of the lesions. The full healing was defined upon the total closure of the injury without evidence of residual exudates or inflammation. The patients returned for a clinical and cosmetic evaluation and photographic documentation at 7, 14, 21 and 60 days.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Phenytoin

### **Primary outcome(s)**

For each treatment group, measured at 7, 14, 21 and 60 days:

1. Pain of treatment performed, scored on a visual analogue scale (VAS): 0 (ausente); + (mild); ++ (moderate); +++(greater)
2. Shape and thickness of the scar using the following scale: A = less than 70% elliptic and flat; B = greater than 70% circular and flat; C = less than 10% hypertrophic

3. Cosmetic outcomes; the criteria for evaluation were as follows: excellent, no noticeable scar; good, slightly noticeable scar with normochromia or hypochromia; poor, depressed scar or intense dyschromia

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

1. Efficiency of the method, based on evaluations made by the physician and on the comparative photographic documentation
2. Adverse reactions; causative agents of allergic contact dermatitis was observed by the presence of erythema and vesicles

The computer application was specifically developed for measuring the cutaneous wound area and scars on digital images. Afterwards, the software automatically calculated its area in mm<sup>2</sup>.

### **Completion date**

01/05/2009

## **Eligibility**

### **Key inclusion criteria**

1. Bearing two or more skin lesions clinically compatible with melanocytic naevi, located in the region of the face or back of the chest
2. Cared at Hospital Santa Casa de Misericórdia in Curitiba
3. Male or female, aged 16 years and older
4. Assessing the possible need for surgical removal of nevi, when they present at least one of the following changes:
  - 4.1. Itching
  - 4.2. Changes in pigmentation
  - 4.3. Inflammation
  - 4.4. Bleeding
  - 4.5. Located in the area of trauma
  - 4.6. Aesthetic reasons

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Sex**

All

### **Total final enrolment**

100

## Key exclusion criteria

1. Immunosuppression
2. Chronic renal insufficiency
3. Serious coagulopathies
4. Have a history of adverse effects caused by phenytoin

## Date of first enrolment

16/03/2007

## Date of final enrolment

01/05/2009

## Locations

### Countries of recruitment

Brazil

### Study participating centre

Department of the Dermatology Service

Curitiba

Brazil

80010-030

## Sponsor information

### Organisation

Hospital Santa Casa de Curitiba (Brazil)

### ROR

<https://ror.org/01by1qv45>

## Funder(s)

### Funder type

University/education

### Funder Name

Federal University of São Paulo (Universidade Federal de São Paulo) (Brazil)

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	24/08/2010	29/12/2020	Yes	No