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Assessment of the effect of phenytoin on cutaneous healing

Submission date 18/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/12/2009	**Overall study status** Completed	
Last Edited 29/12/2020	**Condition category** Cancer	

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^2.

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?
Results article	results	24/08/2010	29/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes