Does the application of topical chloramphenicol ointment (chloromycetin) to sutured wounds reduce the incidence of wound infection following minor surgery?

Submission date 02/04/2007	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/07/2007	Completed	[X] Results
Last Edited 19/01/2009	Condition category Infections and Infestations	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Clare Heal

Contact details

10, Sunset Beach Court Shoal Point Mackay Australia 4740

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Heal001

Study information

Scientific Title

Study objectives

Although the use of topical antibiotics after minor dermtological surger is widespread, it does not decrease the incidence of wound infection.

Ethics approval required

Old ethics approval format

Ethics approval(s)

James Cook University Ethics Committee, approved on 28th March 2007 (ref: H2590)

Study design

Randomised, controlled, double-blinded trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Wound infection

Interventions

A single application of topical chloramphenicol ointment versus topical paraffin ointment following minor surgery.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Infection. The wounds will be assessed for infection at time of removal of sutures (5-14 days).

Secondary outcome measures

No secondary outcome measures

Overall study start date

10/04/2007

Completion date

10/04/2008

Eligibility

Key inclusion criteria

All patients presenting to a participating GP for excision of a minor skin lesion (all body sites).

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

948 (474 in each group)

Key exclusion criteria

- 1. Already taking oral antibiotics
- 2. Oral or topical antibiotics clinically indicated immediately postoperatively
- 3. Lacerations
- 4. Having a flap or two layer procedure
- 5. Having excision of sebaceous cyst
- 6. History of allergy to any of ingredients of chloromycetin ointment
- 7. Personal or family history of aplastic anaemia

Date of first enrolment

10/04/2007

Date of final enrolment

10/04/2008

Locations

Countries of recruitment

Australia

Study participating centre 10, Sunset Beach Court

Mackay

Sponsor information

Organisation

James Cook University, School of Medicine (Australia)

Sponsor details

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Townsville Australia OLD 4811

Sponsor type

University/education

ROR

https://ror.org/04gsp2c11

Funder(s)

Funder type

University/education

Funder Name

James Cook University, Primary Health Care Research and Development Fund (Australia)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults15/01/2009YesNo