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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/07/2007	**Overall study status** Completed	
Last Edited 19/01/2009	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Australia
4740

Sponsor information

Organisation
James Cook University, School of Medicine (Australia)

Sponsor details
-
Townsville
Australia
QLD 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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/01/2009		Yes	No