

Does a single application of topical chloramphenicol to sutured wounds reduce the incidence of infection?

A prospective double blinded randomised controlled trial

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Background: Wound infections

- **Previous research in minor surgery in Mackay: 8.6% infection rate¹**
- **South Australian GP practice cohort: 1.9%²**
- **Victorian skin cancer clinic: 1.5%³**
- **French dermatology clinic: 2.0%⁴**

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Background: Topical chloramphenicol



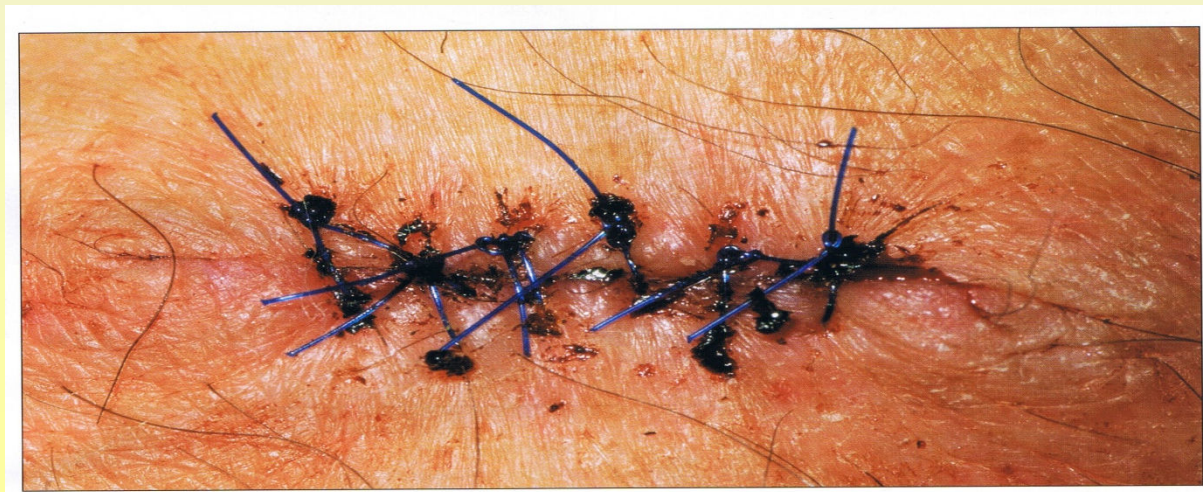
- **Chloromycetin or Chlorsig**
- **Ointment 10 mg/g chloramphenicol**
- **Topical ocular chloromycetin used in UK and Australia**
- **66% (1999) and 72% (2010) of UK plastic surgeons use chloramphenicol eye ointment in some capacity.¹**
- **Under-powered RCT: application following hip replacement – 4/47 versus 8/45²**

¹Erel E, Platt A, Ramakrishnan V. Chloramphenicol use in plastic surgery. Br J Plast Surg 1999;52:326-327 & Erel E, Goodyear S, and Misra A. Chloramphenicol use in plastic surgery: a follow-up. JPRAS 2010; 63: e102-e103.

²Kamath S, Sinha S, Shaari E, Young D, Campbell AC. The role of antibiotics in hip surgery. A prospective randomised study. Injury 2005; 36(6):783-787.

Clinical Question

Does application of topical chloramphenicol to sutured wounds reduce the incidence of wound infection?



Setting

- JCU - Mackay Rural Clinical School
- Mackay's population about 80,000
- 104 practicing GPs
- No resident dermatologist or plastic surgeon



Design

Prospective double-blind randomised controlled trial



Recruitment and Participants



- **15 GPs in 3 practices; one skin cancer clinic**
- **Data collection between June 2007 and May 2008**
- **Consecutive patients presenting for minor skin excision**
- **Practice nurses responsible for recruitment, randomisation and data collection**



Eligibility criteria



Inclusion

- Minor skin excision
- Lacerations
- Sutured cysts
- Flap/2 level
- All body sites

Exclusion

- Oral/topical antibiotics
- Immuno-suppressants
- Inflammed incised sebaceous cysts
- Family history of aplastic anaemia
- History of allergy to chloromycetin ointment

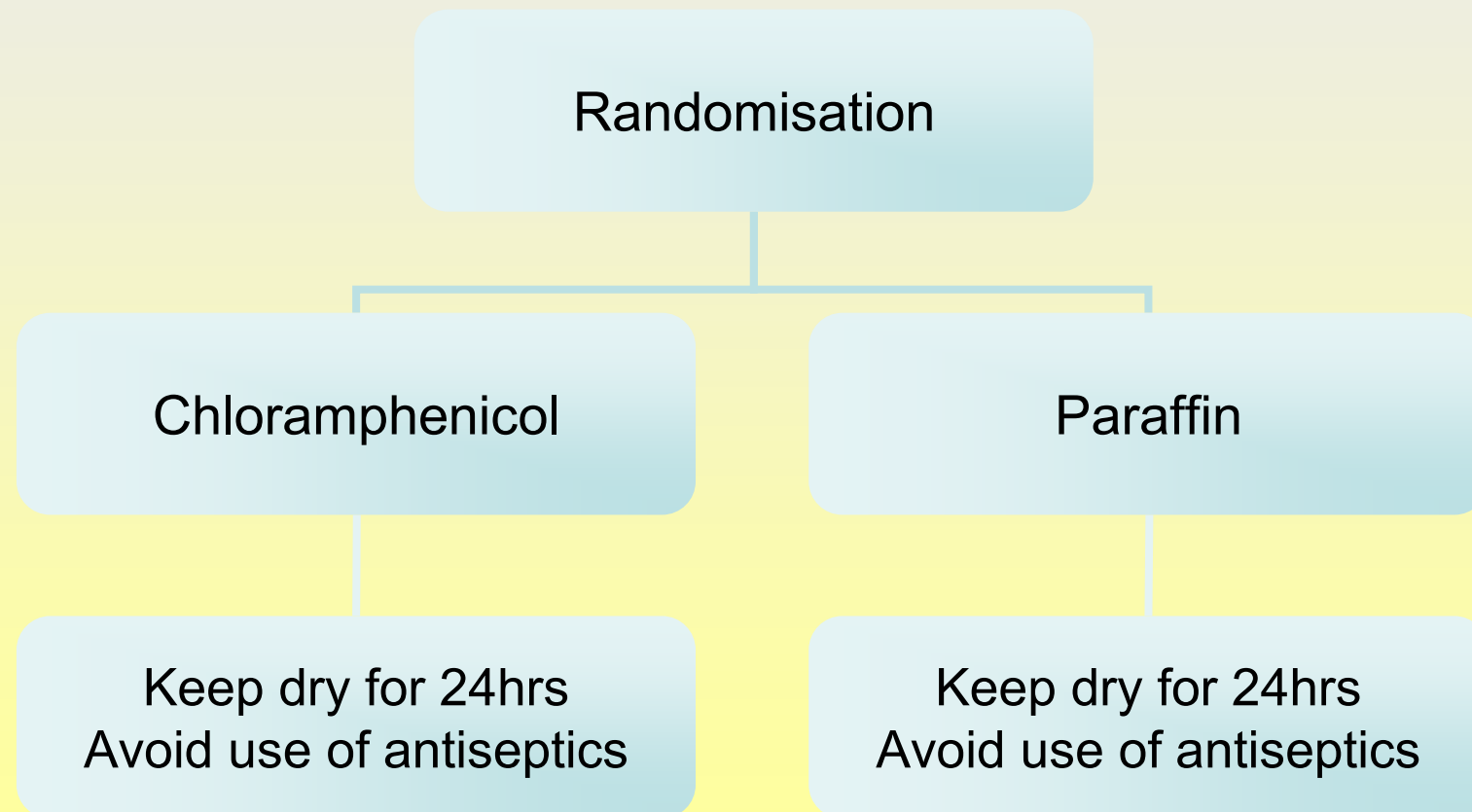
Sample size

- Based on previous infection rate:
10% reduction to 5% “clinically significant”
- Sample size **946** (473 per group) to reach power in excess of 80%; significance level 0.05

Surgical wound management protocol

- Skin preparation - normal saline **or** chlorhexidine
- Sterile technique, including sterile gloves
- Local anaesthetic – type and volume recorded
- Suture material – nylon
- Dressing – melolin and tape
- No antibiotics, neither topical nor oral; no topical antiseptics; no antiseptic washes; no medicated soaps
- Removal of sutures – back 10 days, other sites 7 days

Intervention process



Clinical outcome measure

- CDC National Nosocomial Infection Surveillance System definition of superficial surgical site infection – standardized surveillance criteria:

- 1. Infection within 30 days**

Involves only skin or subcutaneous tissue

- 2. a. Purulent discharge from wound, or**

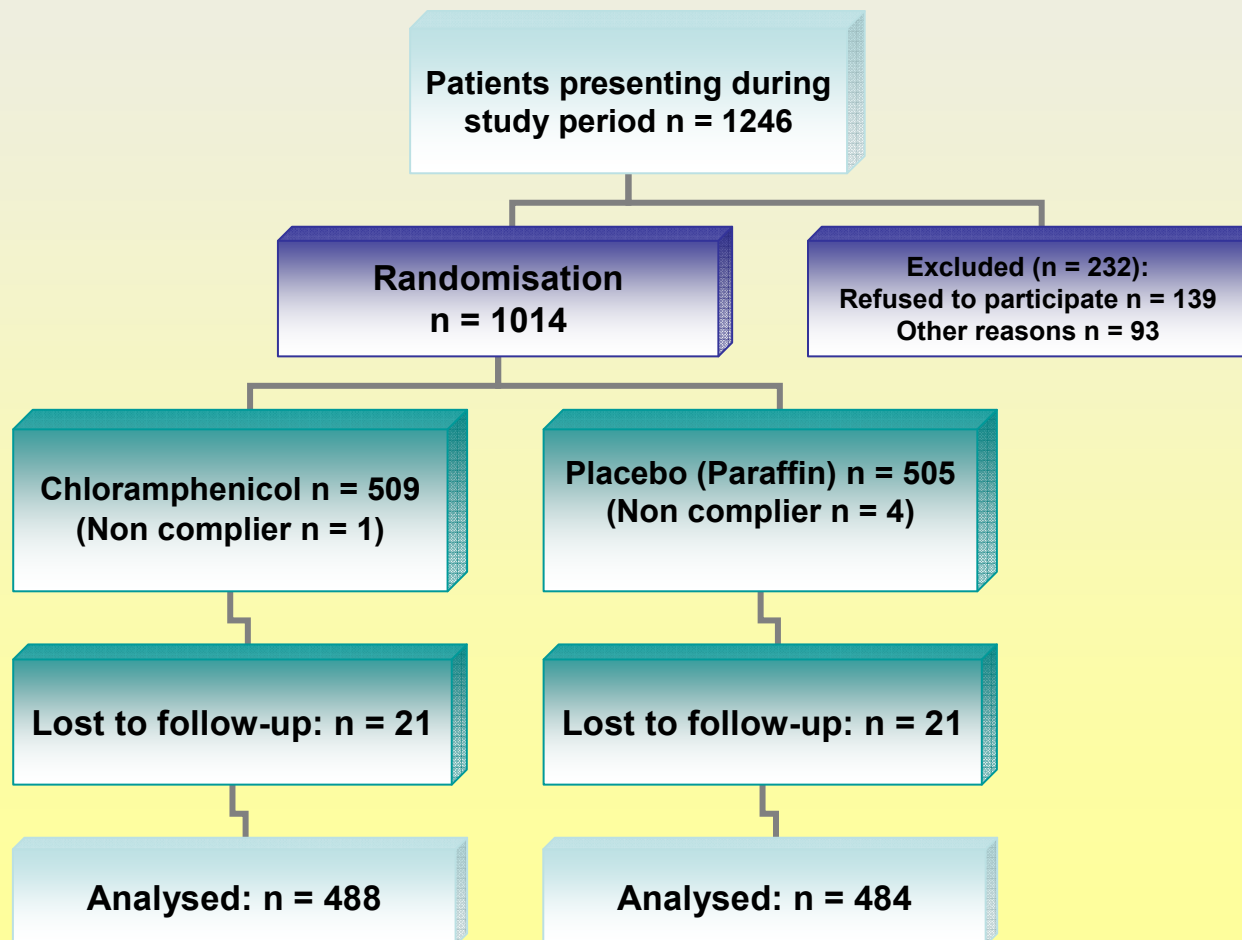
b. Positive culture, or

c. Doctor diagnoses infection

- 3. Stitch abscess does not count as infection**

- Rather vague – but “gold standard”

Results – Participants' flow chart



Results – Baseline comparisons



	Intervention (n=488)	Control (n=484)
Mean age (SD)	59.5 (23.2) yrs	59.0 (27.5) yrs
% Male	54.5%	54.1%
% Current smoker	16.6%	15.7%
% Diabetes mellitus	7.6%	10.4%
% Other medical condition	16.5%	18.1%
% Trunk	22.1%	21.1%
% BCC, SCC, or SK	71.7%	65.1%
Mean length of excision (SD)	20.9 (25.6) mm	21.0 (28.8) mm
Median ROS (IQR)	7 (7-9) days	8 (7-10) days

Results – Infection rates

- **Paraffin** (control) 53/484; **11.0%** 95%-CI = [7.7,14.2]
- **Chloramphenicol** (intervention) 32/488; **6.6%** 95%-CI = [4.8, 8.3]
- **40% reduction in infection statistically significant**
p=0.001
- Absolute reduction (4.4%) did not reach pre-determined level for clinical significance (5%)

Discussion: Limitations of study

- **Diagnosis of infection subjective**
- **Surgical training and techniques of GPs**
- **No arm with no ointment applied**
- **Single dose of ointment only**
- **Generalisability might be limited**

Discussion: Side effects

- **Allergic contact dermatitis^{1,2,3}**
- **Antibiotic resistance³⁻⁵**
- **Aplastic anaemia^{6,7}**

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Discussion – Antibiotic prophylaxis

- **Efficacy, antibiotic costs, adverse effects and resistance**
- **The results of this study could encourage the judicious use of topical antibiotics following minor skin surgery**

Conclusion

The present study suggests that the application of a single dose of topical chloramphenicol to sutured wounds following minor surgery produces a moderate (11% to 6.6%) reduction in infection rate which was statistically but not clinically significant.

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