

A randomized trial comparing Octyl-cyanoacrylate and subcuticular sutures for post-auricular wound cosmesis

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Registration date 28/09/2007	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 27/10/2015	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

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
N0227186102

Study information

Scientific Title
A randomized trial comparing Octyl-cyanoacrylate and subcuticular sutures for post-auricular wound cosmesis

Study objectives

Is there a difference in the cosmetic appearance of post-auricular wounds closed using Octyl-cyanoacrylate or subcuticular sutures at 3 months, as judged by a visual analogue scale assessment of photographs by assessors blinded to treatment allocation?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Ear

Interventions

Patients will be given the Patient Information Leaflet and informed consent will be obtained on enrolment, this will take place at the time of being listed for surgery. Demographic details will be listed on the Wound Evaluation Proforma at the time of enrolment and include age, sex, and hospital number.

Patients will be randomized, using a random numbers table, to one of two methods of skin closure, subcuticular 4-0 vicryl sutures or octyl-cyanoacrylate (Dermabond).

The operating surgeons will be given instruction on using octyl-cyanoacrylate by the Dermabond Representative.

The operating surgeon will not be aware of which arm of the study the patients will be assigned to at the time of consenting the patient. The post-auricular wounds will be closed by ENT surgeons operating at a single teaching hospital. The time taken to close the skin will be measured in seconds from the time of picking up to laying down of the surgical instruments, and this will be recorded on the wound evaluation proforma to the nearest tenth of a second. A single intra-operative dose of intravenous Co-amoxiclav 1.2g will be given to all patients, unless they are penicillin allergic in which case Clarithromycin 500mg will be used. A head bandage will be applied in theatre on completion of the procedure and will be removed the following day. Patients will be discharged from hospital on the first post-operative day.

All patients will be followed-up in the ENT clinic at 3 weeks post-operatively for removal of dressings from the external auditory canal as per current practice. At this point the clinician will record on the Wound Evaluation Proforma: any history or signs of wound infection, wound dehiscence or antibiotics prescribed post-operatively. All patients will be followed-up again in the ENT clinic at 3 months post-operatively as per current practice. At this point 1 standard photo will be taken of the wound, and the wound will be assessed by the principal investigator

using the validated Hollander Wound Evaluation Scale (HWES), which assesses 6 clinical variables: step-off borders, contour irregularities, scar width, edge inversion, excessive inflammation and overall cosmesis. Each category is assigned a score of 1 or 0. A score of 0 is considered optimal, a score of 1-6 suboptimal. This will be recorded on the Wound Evaluation Proforma. During the evaluation and photography the assessor will be blinded to the method of skin closure used. Other clinical variables that will also be recorded on completion of the HWES will include the specific procedure the patient has undergone, the method of skin closure, whether the patient has worn glasses post-operatively, and whether they are a smoker.

The data collection is expected to be complete approximately 9 months later, in January 2007. The photos of the wounds will then be compiled and judged by 2 independent surgeons who have an interest in facial surgery and blinded to treatment allocation. A validated cosmesis visual analogue scale will be used, comprising of a 100mm line with 'worst scar' on the left end and 'best scar' at the right end. A mark placed along the line is measured in millimetres from the left margin, and this constitutes the score. The higher the score the better the cosmesis.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Octyl-cyanoacrylate

Primary outcome(s)

Cosmetic appearance of post-auricular wounds as judged by a visual analogue scale assessment of photographs by assessors blinded to treatment allocation.

Key secondary outcome(s)

1. Time taken for skin closure (seconds)
2. Early wound complication (infection, dehiscence) assessed at 3 weeks
3. Cosmetic appearance of post-auricular wounds as judged by the Hollander Wound Evaluation Scale assessed at 3 months

Completion date

28/02/2007

Eligibility

Key inclusion criteria

This sample aims to have 80% power to detect a statistically significant difference between groups with 95% confidence if the true difference between treatment outcomes is at least 0.5 of a standardised difference (ie approximately 8mm on the visual analogue scale). This will require 125 patients in the final analysis. We aim to recruit 140 patients to allow for 10% loss to follow-up. Support was provided by Dr Bellamy in calculating the sample size.

Inclusion criteria will be adult and paediatric patients undergoing ear surgery using a post-auricular incision.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Revision surgery, acute mastoiditis, diabetes mellitus, coagulopathy, personal or family history of keloid or hypertrophic scar formation, reopening of the wound eg for drainage of wound haematoma, allergy to skin glue.

Date of first enrolment

01/04/2006

Date of final enrolment

28/02/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

South Tees NHS Hospitals Trust

Middlesbrough

United Kingdom

TS4 3BW

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

South Tees Hospitals NHS Trust (UK)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes