ISRCTN96030942 https://doi.org/10.1186/ISRCTN96030942

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

Submission date 28/09/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/09/2007	**Overall study status** Stopped	
Last Edited 27/10/2015	**Condition category** Surgery	

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
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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