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Dissolvable versus non-dissolvable stitches for traumatic cuts of the face

Submission date
13/03/2021

Recruitment status
No longer recruiting

Registration date
16/03/2021

Overall study status
Completed

Last Edited
09/10/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Injuries to the face often require repair with stitches (sutures). This is particularly the case where wounds may be open or where the wound edges are not well aligned. Sutures contribute to wound healing by ensuring that wound edges are well aligned, to minimise the amount of new tissue that the body has to produce. This process of healing, where there is no tissue loss, is known as healing through primary intention. The benefit of this process, compared to healing through secondary intention, where new tissue must be created by the body, is that the wound will heal will less scarring, and will retain reasonably normal function (in terms of tissue strength) after healing.

There are different choices for which type of suture material may be used in the treatment of wounds to the face. One key question is whether it is better to use a material that dissolves over time, or whether to use a material that will not dissolve. Suture materials that dissolve over time (defined as resorbable) offer the advantage that patients do not require a second visit to a doctor or nurse for suture removal. However, there is some argument that resorbable sutures do not support the tissue effectively to allow proper healing and lead to more infections, though there is no clear evidence supporting these arguments. At present, surgeons who repair cuts to the face may use either type of suture depending on their own experiences and preferences.

The aim of this study is to compare the healing of patients with facial wounds (lacerations) who have been treated either with resorbable sutures or non-resorbable sutures. At six months after repair, patients and doctors would then look at how the injury has healed. This would allow us to understand whether there is a difference in healing between resorbable and non-resorbable sutures, and which kind of suture gives patients the best outcomes. Ultimately, this will allow surgeons to use the most appropriate suture, and to make sure that patients get the best, and the same care, whoever does their operation. The results would either allow us to change practice to prevent unnecessary visits for suture removal or would present us with justification for doing so.

Who can participate?
Adults presenting to the emergency department with facial lacerations

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given. Participants in the first group will have their facial lacerations closed with Vicryl Rapide (a type of resorbable suture) and the second group of participants will have their facial lacerations closed with Ethilon (a type of non-resorbable suture)

What are the possible benefits and risks of participating?
This trial will not introduce any additional risk or burden to participants. Any inconvenience will be minimised by virtual follow-up at participant convenience.

Where is the study run from?
Cambridge University Hospitals (UK)

When is the study starting and how long is it expected to run for?
October 2020 to March 2024

Who is funding the study?
British Association of Oral and Maxillofacial Surgeons (BAOMS) research grant (UK)

Who is the main contact?
Dr Shadi Basyuni, shadi.basyuni@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

289842

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 289842

Study information

Scientific Title
Trial Of Resorbable versus Non-Resorbable sutures for traumatic lacerations of the face (TORN Face)

Acronym
TORN Face

Study objectives
1. There is no difference in cosmetic outcome or complication rate between resorbable and non-resorbable sutures
2. Resorbable sutures are associated with better patient report outcomes and cost analysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/05/2021, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048270; cambridgecentral.rec@hra.nhs.uk), ref: 21/EE/0097

Study design
Single-centre single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Facial lacerations in patients with facial trauma

Interventions
This study is a single centre, single-blinded randomised controlled trial with 2 treatment arms:
1. Resorbable (Vicryl Rapide)
2. Non-resorbable sutures (Ethilon).

The trial will recruit participants who present to the Emergency Department of Cambridge University Hospitals NHS Foundation Trust with a traumatic laceration affecting the face. Following enrolment in the study, suitability for randomisation will be determined by the operator initially reviewing the patient. For randomisation, the site of facial laceration will be required.

Patient randomisation will be performed by way of sealed envelope randomisation as the only viable means. A pseudorandom number generator will be used to initially assign groups to predetermined sequentially ranked envelope numbers (to detect any attempts to allocate to patients out of sequence). Randomised envelopes containing either treatment arm will be produced prior to trial recruitment and deposited in a safe location within the emergency department and urgent treatment centre. The preceding use of randomised envelopes reduces the delay of using real-time randomisation technologies that may further contribute to delayed patient care. Blocked randomisation will be used, with a block size of 4 and allocation ratio 1:1, and subjects allocated randomly within each block. Allocation codes will be held by an independent clinician on an anonymised database, so as not to compromise integrity of randomisation. Following allocation,patient details with allocation code will again be entered into the database by an independent clinician; these details will need to be relayed to the designated independent clinician through email for entry into the secure database.

Patients, relatives and treating physicians cannot be blinded due to the nature of the intervention (clinicians are acutely aware of the differences in appearance and handling properties of resorbable and non-resorbable sutures, and patients will be provided with different post-operative information according to the treatment arm of allocation). Follow-up images will be collected centrally (Cambridge) using a secure department-specific email address and a REDCap database designated for this purpose. Outcome scores will be determined by two outcome adjudicators independently, who will be blinded to the allocation of patients. Any disagreement will be determined by a third independent adjudicator, who will also be blinded to allocation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Cosmetic outcome measured using a visual analogue cosmesis scale (VAS) to assess cosmetic results from patient images sent in for their electronic medical records at 6 months

Secondary outcome measures
1. Complication rate measured using a review of medical notes at 6 months
2. Patient-reported outcome measured using a telephone interview to discuss overall satisfaction of care at 6 months
3. Cost-benefit analysis measured using a review of medical notes at 6 months

Overall study start date

01/10/2020

Completion date
27/08/2023

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the trial
2. Aged ≥18 years
3. Diagnosed with a traumatic laceration affecting the facial region

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
200

Key exclusion criteria
1. Wounds with the following characteristics:
1.1. Significant contamination or presenting later than 12 h after the initial injury
1.2. Animal or human bites
1.3. Wounds requiring antibiotic prophylaxis
1.4. Wounds amenable to closure with adhesive tape or tissue adhesive
1.5. Complex lacerations requiring closure under general anaesthetic
1.6. Not amenable to primary closure (significant tissue loss requiring more complex closure methods)
1.7. Lacerations involving cartilage or bony injuries
1.8. Injuries involving parotid gland, parotid duct, or facial nerve
1.9. Wounds requiring smaller than 5/0 suture material
2. Scalp lacerations due to difficulties in assessing the cosmetic outcome
3. Presence of accompanying injury/polytrauma requiring more extensive medical/surgical intervention as a priority
4. History of:
4.1. History of keloid or hypertrophic scar formation
4.2. Collagen vascular disorders
4.3. Prolonged corticosteroid use
4.4. Type I diabetes or poorly controlled type II diabetes

4.5. Primary or secondary immunodeficiency (including systemic chemotherapy)
4.6. Clotting or bleeding disorders
4.7. Allergy to chloramphenicol 1% ointment
4.8. Recent radiotherapy to the head and neck
5. Unable to give written informed consent, including patients considered under the influence of alcohol (or recreational/medicinal substances) at the time of patient consultation

Date of first enrolment
01/07/2021

Date of final enrolment
06/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website

cuh.nhs.uk

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research organisation

Funder Name
British Association of Oral and Maxillofacial Surgeons

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the risk of breach of patient confidentiality (clinical photographs)

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No