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

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
13/03/2021		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
16/03/2021		☐ Results		
Last Edited		Individual participant data		
09/10/2023	Injury, Occupational Diseases, Poisoning	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

#### Contact name

Dr Shadi Basyuni

#### **ORCID ID**

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# Additional identifiers

# EudraCT/CTIS number

Nil known

#### **IRAS** number

#### 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

## 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

Hills Road Cambridge England United Kingdom CB2 0QQ +44 (0)1223 348 494 research@addenbrookes.nhs.uk

## 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