ISRCTN27023864 https://doi.org/10.1186/ISRCTN27023864

Scar study

Submission date	Recruitment status	[_] Prospectively registered
22/09/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/10/2016	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/12/2020	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Scars are areas of fibrous (made up of fibres) tissue that replace normal skin after injury. A scar is a natural result of the healing process, and comes from the biological process of wound repair in the skin and other tissues of the body. With the exception of very minor lesions (cuts), every wound (e.g. after accident, disease, or surgery) results in some degree of scarring. There is a lack of a clear understanding of the processes involved in fibrosis (the thickening of connective tissue) and scar formation and research directed towards technologies that can lead to scar reduction are lacking.The Queen Victoria Hospital (QVH) is a regional centre for burns and plastic surgery. The hospital treats patients with acute (sudden) wounds and those undergoing surgical reconstruction and scar revision. As part of this treatment scar tissue will often be removed and disposed of as clinical waste. The aim of this study is to look at these discarded scars in order to investigate how the different molecules affect the development of human scars.

Who can participate?
Adults who are going to have a scar surgically removed or released (releasing a tight scar to improve movement)

What does the study involve?
Potential participants are approached by the research team after a consultant plastic surgeon has planned their scar revision surgery. An information sheet and explanation about the study is given by a member of the research team so that the participant can decide if they want to take part. Two weeks before surgery, a researcher contacts the potential participant and gains consent. The participant has surgery as planned and the tissue that is removed is collected. The participant also gives a blood sample and additional consent for a punch biopsy (having a small sample taken with a circular blade) to be taken from an area of normal skin next to the scar. Before undergoing surgery, participants also complete a questionnaire about how they got the scar in the first place.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Queen Victoria Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2016 to January 2026

Who is funding the study?
Queen Victoria Hospital NHS Foundation Trust (UK)

Who is the main contact?
Mr Simon Booth
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Contact information

Type(s)
Public

Contact name
Mr Simon Booth

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V0.6

Study information

Scientific Title
What is the pattern and interrelationship between the biomarkers of scarring and fibrosis and the observed phenotypic scarring severity

Study objectives
The aim of this study is to investigate the pattern and interrelationship between the biomarkers of scarring and fibrosis and the observed phenotypic scarring severity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast - Brighton & Sussex Research Ethics Committee, 15/03/2016, ref: 16/LO/0372

Study design
Observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Cutaneous scarring

Interventions
Potential participants will be approached by the research team after a consultant plastic surgeon has planned scar revision surgery. An information sheet and explanation about the study will be given by a member of the research team. Two weeks before surgery, a researcher will contact the potential participant and gain consent.

Prior to surgery participants will complete a short scar assessment questionnaire, which investigates the origin of the scar as well as patient demographics and scar assessment by an experienced clinician. After the scar tissue is excised during surgery, the sample will be transferred to the research laboratory, cut into sections and examined using histological and immunological stains. The patient will not receive any follow up outside of standard care.

Intervention Type
Mixed

Primary outcome measure
Scar severity is measured using modified Vancouver scar scale, Patient and Observer scar scale and the Manchester scar scale before surgery.

Secondary outcome measures

Expression of Biomarker level in scar sample biopsy is measured using semi quantitative immune-histochemistry and gross morphology of skin section using histological stains at the time of surgery.

Overall study start date
01/03/2016

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Aged over 18
2. Patients with a scar suitable for surgical excision

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned number of participants = 300

Key exclusion criteria
Not meeting exclusion criteria

Date of first enrolment
09/09/2016

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Victoria Hospital
Holtye Road
East Grinstead
United Kingdom
RH19 3DZ

Sponsor information

Organisation
Queen Victoria Hospital NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03bs2yy11

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Queen Victoria Hospital NHS Foundation Trust

Funder Name
Blond McIndoe Research Foundation

Alternative Name(s)
Blond McIndoe Foundation, Blond McIndoe, BMRF

Funding Body Type

Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Simon.booth@qvh.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

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