

ANTICS: Antibiotic implant in cardiac surgery

Submission date 17/02/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 17/02/2011	Overall study status Completed	☐ Protocol
Last Edited 11/05/2017	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☐ Results
		☐ 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

9514

Study information

Scientific Title

A randomised, controlled, patient and assessor blind pilot study of a collagen implant (GentaFleece™) for the prevention of sternal wound infection in cardiac surgery

Acronym

ANTICS

Study objectives

The study aims to assess the role of local treatment with a collagen-gentamicin implant in the reduction of sternal wound infections in a cardiac surgical population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved, ref: 10/H0206/30

Primary study design

Interventional

Study design

Single-centre randomised interventional pilot/feasibility study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions

GentaFleece™: antibiotic-impregnated collagen fleece inserted at closure of sternal wound following cardiac surgery.

Follow-up length: 2 months

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

GentaFleece™

Primary outcome(s)

ASEPSIS score, measured at day 2, day 4 and week 8 following surgery

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/12/2011

Eligibility**Key inclusion criteria**

1. Aged 18 years or older, either sex
2. Undergoing cardiac surgery through the sternum (sternotomy)
3. Provided informed consent to participate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients admitted for emergency surgery
2. Pregnant or lactating females
3. Patients with a known hypersensitivity to collagen and/or gentamicin and other aminoglycoside antibiotics
4. Patients with a history of autoimmune diseases in which gentamicin is contraindicated (e.g., Parkinson's disease or myasthenia gravis)
5. Serum creatinine more than 200 µmol/l within 2 weeks pre-operatively
6. Chronic renal failure on dialysis
7. Participating in another clinical research study

Date of first enrolment

29/11/2010

Date of final enrolment

30/12/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Derriford Hospital

Plymouth

United Kingdom

PL6 8DH

Sponsor information

Organisation

Plymouth Hospitals NHS Trust (UK)

ROR

<https://ror.org/05x3jck08>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
HRA research summary			28/06/2023	No	No