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ANTICS: Antibiotic implant in cardiac surgery

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-centre randomised interventional pilot/feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
29/11/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 200; UK sample size: 200

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
England

United Kingdom

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Plymouth Hospitals NHS Trust (UK)

Sponsor details
Derriford Hospital
Derriford Road
Plymouth
England
United Kingdom
PL6 8DH

Sponsor type
Hospital/treatment centre

Website
http://www.plymouthhospitals.nhs.uk/Pages/Home.aspx

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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