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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

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

Study design
Single-centre randomised interventional pilot/feasibility study

Primary study design
Interventional

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