



ANTICS

Antibiotic Implant in Cardiac Surgery

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ANTICS - Background

- Sternal wound infection following cardiac surgery 2-8%
- Significant impact on mortality/morbidity
 - Antibiotics
 - Additional procedures
 - Length of stay
 - Reconstruction
- Meticulous stable fixation and antibiotic prophylaxis

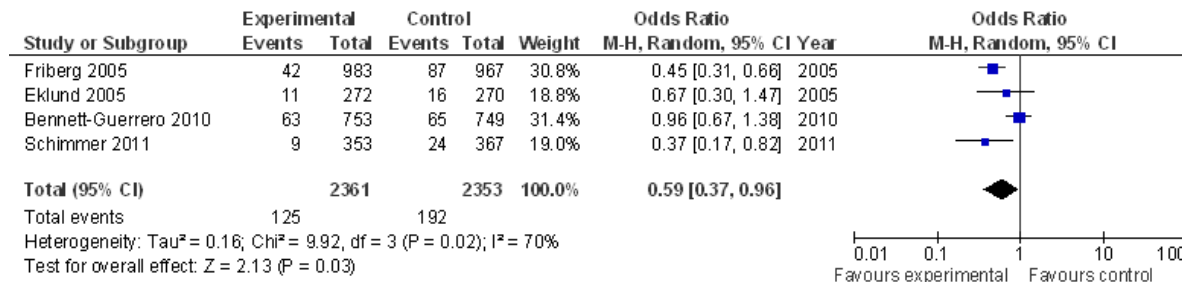
ANTICS - Gentafleece

- Gentafleece™ (Baxter UK)
- Gentamicin-impregnated collagen implant
- 90 mg Gentamicin for slow local release over 1 – 3 days
- Minimal increase in plasma concentration
- Additional to antibiotic prophylaxis and standard measures



Effectiveness of a gentamicin impregnated collagen sponge on reducing sternal wound infections following cardiac surgery: a meta-analysis of randomised controlled trials

S Creanor¹, A Barton², A Marchbank³



Revised Data (2013): Pooled data analysis assessing incidence of all post-surgery sternal wound infections in all participants.

Random effects model as evidence of significant heterogeneity (I²=70%).



ANTICS - Objective

- To provide information for planning a definitive trial investigating clinical and cost-effectiveness of gentamicin-impregnated collagen implants (Gentafleece™) to reduce sternal wound infections after cardiac surgery

RfPB Ref: PB-PG-0808-15115

South West 2 Research Ethics Committee 10/H0206/30



ANTICS - Methods

- Single-centre
- Randomised
- Controlled
- Patient and assessor-blind
- Pilot study
- 200 patients randomised (1:1) prior to closure:
 - treatment-as-usual (TAU)
 - Genta fleece into sternal wound
- Blind assessment of wounds during hospital stay and by patient-reports at 8 weeks
- Recruitment between November 2010 and August 2011




ANTICS - Outcomes

- ASEPSIS
- Wound infection rate (CDC 1992)
- Reoperation rate
- Readmission rate
- LOS
- Mortality
- EQ-5D
- Incremental cost effectiveness ratio



ANTICS - Results

- Wound checks as planned on Days 2 and 4 for 98% (195/200) of participants
- 2 deaths
- Post-operative complications, duration of ventilation, ICU and hospital stays similar for both groups
- Average length of time in level 1 longer in TAU:
 - Gentafleece: 9 (6-17) days
 - TAU: 13.5 (6-32) days
- Readmission rates similar
- Little evidence of sternal wound infection (SWI) at Day 2 or Day 4



	Gentafleece (n=98)	TAU (n=102)
8 weeks follow-up	97% (95/98)	98% (100/102)
At least one reoperation	8.2% (8/98)	12.8% (13/102)
Problem with healing	17.9% (17/98)	23.5% (23/102)
At least one readmission	14.6% (14/98)	17.7% (18/102)
Median and IQR ASEPSIS	2.5 (0-7.5)	5 (0-12.5)
Minor infection (ASEPSIS 21-30)	1%	10%
Moderate infection (ASEPSIS 31-40)	1%	2%
All SWI*	15%	22%
Deep SWI*	3%	7%

* Based on clinical review of all available evidence



ANTICS - Results

- Economic evaluation: main cost drivers associated with in-patient stay (90% of average cost/patient)
- Average additional cost associated with a sternal wound infection £2439
- Planned collaborative subsidiary analysis of ASEPSIS data not forthcoming
- Pilot study - not powered to detect between-group differences so further statistical analyses were not undertaken



ANTICS – Future Plans

- Multicentre trial in planning
 - 11 centres interested
 - Possible comparative analysis vs Collatamp
 - >3000 patients
 - HE analysis
 - Recent HTA Rapid Call Application unsuccessful



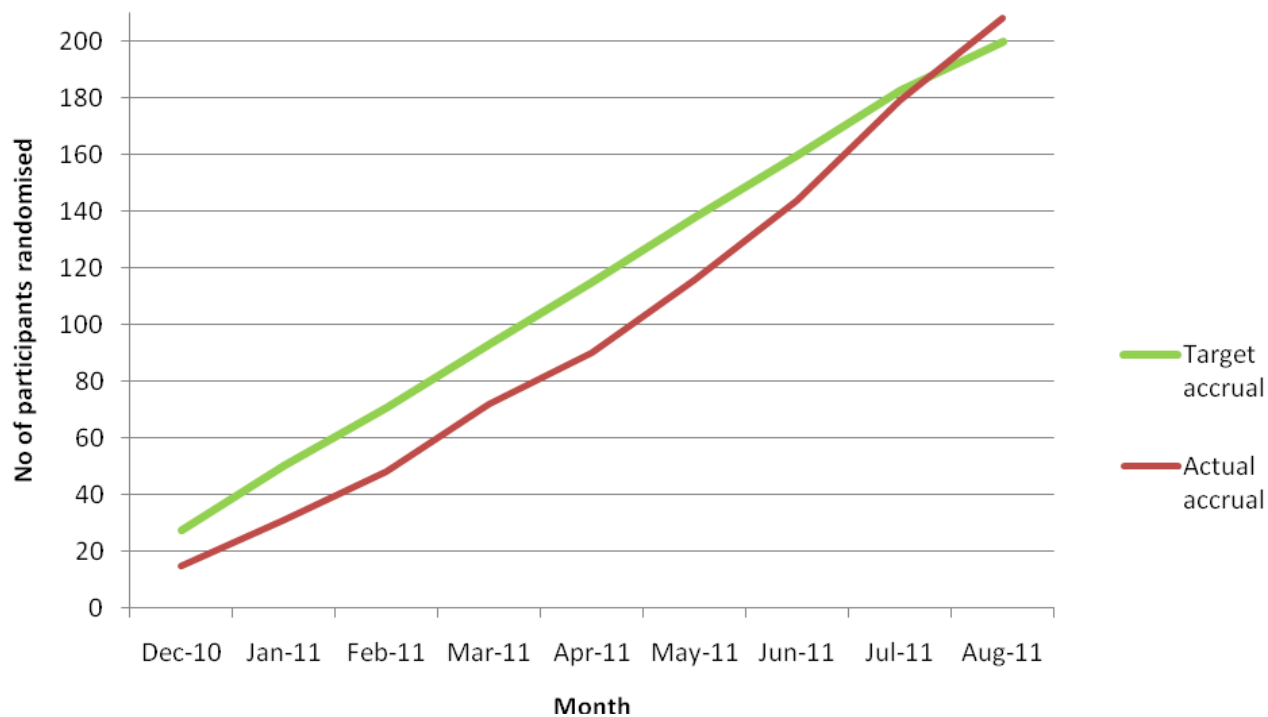
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ANTICS – Subsidiary Slides

ANTICS - Accrual

Target vs Actual accrual
(as of 25th Aug 2011)



ANTICS - Outcomes

ANTICS	PenCTU2009/RS-001	Subject initials:				Subject No.	1	0		
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DAY 2 POST-OPERATION
ASEPSIS WOUND SCORES

Table I: ASEPSIS score for wound healing assessment during the postoperative period.
(Circle one response in each row)

WOUND CHARACTERISTIC	PROPORTION OF WOUND AFFECTED (%)					
	0	<20	20-39	40-59	60-79	>80
Serous exudates	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent Exudate	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

Table II: Additional ASEPSIS score criteria for wound assessment
(Circle scores as appropriate)

Additional treatment	
Antibiotics	10
Drainage of pus under local anaesthesia	5
Debridement of wound (general anaesthesia)	10
Isolation of bacteria	10

IF ANTIBIOTICS WERE GIVEN RECORD THE MEDICATION TAKEN ON THE CONCOMITANT MEDICATION PAGES (28-31)

PLEASE RECORD DETAILS OF CLINICAL FEATURES GIVING RISE TO SCORES IN TABLE AS THEY ARE ELICITED, ON THE ADVERSE EVENTS PAGES (32-37)

ANTICS	PenCTU2009/RS-001	Subject initials:				Subject No.	1	0		
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DAY 2 POST-OPERATION

CDC WOUND CRITERIA

<input type="checkbox"/> Tick which apply		
Superficial Incisional	Yes	No
Local redness		
Local pain		
Local heat		
Local swelling		
Drainage of pus		
Isolation of organisms		
Incision and drainage performed		
Diagnosis of superficial incisional infection made by surgeon/physician		

Deep Incisional	Yes	No
Pus or abscess		
Fever with wound tenderness		
Separation of edges/dehiscence		
Incision and drainage performed		
Other evidence of deep incisional infection		
Diagnosis of deep incisional infection made by surgeon/physician		

Organ/Space Surgical Site Infection	Yes	No
Pus from drain site		
Organisms cultured from space		
Other evidence of organ/space infection		
Diagnosis of organ/space surgical site infection made by surgeon/physician		

REVIEW THE STATUS OF THE PARTICIPANT'S ADVERSE EVENTS AND UPDATE THE ADVERSE EVENTS RECORD ON PAGES 32-37