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Contrast ultrasound study to image the circulation in reconstructive head and neck surgery

Submission date	Recruitment status	[_] Prospectively registered
31/12/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/03/2011	Surgery	

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
P0505

Study information

Scientific Title
A study of power Doppler harmonic imaging in the monitoring of human free-flap tissue perfusion

Study objectives
Contrast harmonic imaging is a superior monitoring method for free flaps compared to standard monitoring.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dorset Research Ethics Committee, approved on 04/05/2005 (ref: 05/Q2201/27)

Study design
Interventional single-arm open crossover pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Free flap reconstruction for head and neck cancer patients

Interventions
Each participant was monitored by both standard procedures and Power Doppler, as follows:
Power Doppler contrast enhanced harmonic imaging was carried out at 12, 24 and 48 hours post-surgery.
Standard monitoring consisted of the following: clinical observation and hand-held non-imaging spectral Doppler (NISD). Standard monitoring was performed for 14 days par participant.

Intervention Type
Procedure/Surgery

Phase
Phase IV

Primary outcome measure

1. Qualitative and quantitative analysis of harmonic imaging at 12, 24 and 48 hours post-surgery
2. Time taken for detection of flap failure compared to standard monitoring within 48 hours post-surgery

Secondary outcome measures
No secondary outcome measures

Overall study start date
19/05/2005

Completion date
19/05/2007

Eligibility

Key inclusion criteria
Patients (both males and females) undergoing head and neck surgery requiring free tissue transfer.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Patients under 18 years
2. Pregnancy and lactation
3. Hypersensitivity to SonoVue®
4. Recent coronary syndrome
5. Ischaemic heart disease
6. Cardiovascular compromise

Date of first enrolment
19/05/2005

Date of final enrolment
19/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Maxillofacial Surgery
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust (UK)

Sponsor details
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mary.burrows@poole.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.poole.nhs.uk/

ROR
https://ror.org/03kdm3q80

Funder(s)

Funder type
Charity

Funder Name
British Association of Oral and Maxillofacial Surgeons (BAOMS) (UK) - clinical research grant

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?
Results article	results	01/12/2010		Yes	No