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# 3D Contrast Enhanced UltraSound in perfusion studies of early renal transplants

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 29/06/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 29/06/2012 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 28/02/2018 | Urological and Genital Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr Ben Stenberg

**Contact details**
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN
+44 191 2336161 Ext: 26552
ben.stenberg@nuth.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
10201

# Study information

## Scientific Title
3D Contrast Enhanced UltraSound in perfusion studies of early renal transplants: a non-randomised study

## Acronym
3D CEUS

## Study objectives
To assess the sensitivity of Three dimensional (3D) contrast enhanced ultrasound (CEUS) of detecting perfusion defects in kidney transplants immediately post-surgery. Also, determine any prognostic value from the haemodynamic factors of the contrast in predicting graft outcome.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=10201

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Newcastle & North Tyneside 2, 10/02/2011, ref: 11/H0907/1

## Study design
Non-randomised; Interventional; Design type: Diagnosis, Not specified

## Primary study design
Interventional

## Secondary study design
Non randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Diagnostic

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

## Interventions
Contrast enhanced ultrasound: Single examination using a 2.4mls injection of Sonovue contrast media.

## Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Perfusion defect rates using 99mTc-diethylenetriamine pentaacetic acid (DTPA) renogram

### Secondary outcome measures
Graft viability up to 3 months post-op measured by serum results and histology reports.

### Overall study start date
04/03/2011

### Completion date
31/07/2012

## Eligibility

### Key inclusion criteria
1. All renal transplant patients that undergo surgery within the collection period for the study until study population is acheived (N=105)
2. Male & Female ; Lower Age Limit 18 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 105; UK Sample Size: 105

### Key exclusion criteria
1. Any patient under 18 years of age
2. A pregnant patient and
3. Any patient excluded due to contraindications as listed in the manufacturers guidelines for the contrast media used

### Date of first enrolment
04/03/2011

### Date of final enrolment
31/07/2012

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Freeman Road**
Newcastle upon Tyne
United Kingdom
NE7 7DN

# Sponsor information

**Organisation**
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

**Sponsor details**
Claremont Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/05p40t847

# Funder(s)

**Funder type**
Charity

**Funder Name**
Northern Counties Kidney Research Fund (UK)

**Alternative Name(s)**

NCKRF

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

**Funder Name**
Society and College of Radiographers (SCoR) (UK)

# 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 | 01/11/2017 | | Yes | No |