

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

Submission date 29/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/06/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/02/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
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

Study type(s)

Diagnostic

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(s)

Perfusion defect rates using 99mTc-diethylenetriamine pentaacetic acid (DTPA) renogram

Key secondary outcome(s)

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

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 achieved (N=105)
2. Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre**Freeman Road**

Newcastle upon Tyne

United Kingdom

NE7 7DN

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

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**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