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The AKI Risk In Derby (ARID) study

Submission date
15/01/2014

Recruitment status
No longer recruiting

Registration date
06/03/2014

Overall study status
Ongoing

Last Edited
24/01/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acute Kidney Injury (AKI) refers to an abrupt drop in kidney function and is often seen in unwell patients who require hospitalisation. In the short term, AKI increases the complexity and duration of treatment and reduces the chance of patient survival. In many patients that do recover, there is also an improvement in kidney function. It is possible that episodes of AKI may have effects on patients in the longer term, leading to kidney damage over time or reducing long-term survival. There is a lack of good quality research in this area. This study intends to find out the long-term effects of AKI on the development and progression of long-term kidney disease as well as the effects of AKI on patient survival.

Who can participate?
Hospitalised patients with similar characteristics, one group who did sustain AKI and one group who did not.

What does the study involve?
Patients will be identified through routine blood tests to measure kidney function that were collected during their hospital stay. They will be invited to participate in the study about three months after these blood tests were taken, by which time they will have recovered from their hospital stay. We will then collect three routine blood tests to measure kidney function: the first at the start of the study (i.e., three months after the episode of AKI to assess the degree of recovery of kidney function); the second at nine months (1 year after the episode of AKI) and the third at 33 months (three years after the episode of AKI). These blood tests can be taken in the community at the patients GP surgery or local blood-taking clinic. Samples from all three blood and urine tests will be stored for further testing. Stored samples will be disposed of at the end of the study. We will confirm the medical details of patients from hospital records and we will monitor health status (including cause of death for any patients who die) through the records kept at the NHS Information Centre.

What are the possible benefits and risks of participating?
Taking part in this study will ensure that the patients kidney function is monitored regularly. This will allow us to pick up any abnormalities and respond to them. The results will be reviewed by our researchers and a specialist doctor. Their GPs will be given advice about how to respond to abnormal results. There are no major disadvantages, risks or side effects. The blood tests will take about 5 minutes of your time and there may be a small amount of discomfort.

Where is the study run from?
The Department of Renal Medicine, Royal Derby Hospital, UK.

When is the study starting and how long is it expected to run for?
The study started in March 2013 and is expected to run for two years.

Who is funding the study?
1. The Bupa Foundation (UK)
2. British Renal Society (UK)
3. Kidney Research (UK)

Who is the main contact?
Dr Nick Selby
nick.selby@nhs.net

Study website
https://www.uhdb.nhs.uk/acute-kidney-injury-risk-in-derby-arid-study/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
13864

Study information

Scientific Title
Defining the long-term consequences of acute kidney injury: the AKI Risk In Derby (ARID) study

Acronym
ARID

Study objectives
The research questions that the study has been designed to address are as follows:
1. Does AKI lead to the onset or progression of chronic kidney disease?
2. Does AKI increase the risk of cardiovascular events?
3. Does AKI confer an increased risk of long-term mortality?
4. Can we develop strategies to identify those patients at higher risk of worse long-term outcomes following an episode of AKI?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/12/2021, Derbyshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8236; derby.rec@hra.nhs.uk), ref: 12/EM/0441

Study design
Non-randomized; Observational; Design type: Case-controlled study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
GP practice, Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details 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
Patients will be identified through routine blood tests to measure kidney function collected during their hospital stay. They will be invited to participate in the study at least two months after these blood tests, by which time they will have recovered from their hospital stay. We will collect three routine blood and urine samples to measure kidney function: the first at recruitment (3 months after the episode of AKI to assess the degree of recovery of renal function); the second at 9 months (1 year after the AKI) and the third at 33 months (three years

after the AKI). These samples can be collected in the community at the patient's GP surgery or local blood-taking clinic. We will retain samples for further testing. We will confirm medical details of patients from hospital records and we will monitor health status (including cause of death for any patients who die) through the records kept at the NHS Information Centre.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 28/03/2017:
Mortality, progression to a combined renal end point (initiation of RRT, GFR<15ml/min/1.73m2, doubling of serum creatinine) at one, three, five and ten years.

Previous primary outcome measures:
CKD progression; Timepoint(s): 1 year and 3 years

Secondary outcome measures
Current secondary outcome measures as of 28/03/2017:
CKD progession defined as ≥25% decline in eGFR plus decline in eGFR stage measred at one, three and five years.

Previous secondary outcome measures:
Mortality; Timepoint(s): 1, 3 and 5 years

Overall study start date
25/03/2013

Completion date
14/04/2026

Eligibility

Key inclusion criteria
1. Age 18-85 years
2. Recent inpatient at Royal Derby Hospital during which a blood test was sent to assess kidney function, and was classified either as AKI or as NAKI (screened for possible AKI but who did not sustain AKI)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
Planned Sample Size: 1084; UK Sample Size: 1084

Total final enrolment
1125

Key exclusion criteria
1. Inability/refusal to give informed consent to participate
2. Language barrier that prevents informed postal consent
3. Death during the same hospital admission that AKI occurred
4. Receiving palliative care

Date of first enrolment
23/04/2013

Date of final enrolment
14/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Derby Hospital NHS Foundation Trust (UK)

Sponsor details

Research and Development Department
Derby City General Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3DT

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
The Bupa Foundation (UK)

Funder Name
British Renal Society

Alternative Name(s)
BRS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Kidney Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Patient feedback meetings to be held in May and June 2017 to update participants on the progress of the study.

Intention to publish date
14/04/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nicholas Selby at Nicholas.Selby@notthingham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1	04/12/2015	22/07/2020	No	No
HRA research summary			28/06/2023	No	No
Interim results article		21/08/2023	07/11/2023	Yes	No
Interim results article		01/05/2022	07/11/2023	Yes	No
Interim results article		01/02/2023	07/11/2023	Yes	No
Interim results article		26/05/2022	07/11/2023	Yes	No
Results article		21/08/2023	24/01/2025	Yes	No