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Pilot trial comparing different fluid amounts given in the earliest stages of treatment in children presenting to UK emergency departments with a severe infection

Submission date
03/08/2016

Recruitment status
No longer recruiting

Registration date
11/08/2016

Overall study status
Completed

Last Edited
18/09/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Septic shock is a life-threatening condition in which the blood pressure drops to dangerously low levels because of a serious blood infection (sepsis). Children are now much more likely to survive a septic shock than ever before. This progress comes from a whole package of treatments including antibiotics, multiple rapid doses (boluses) of fluid (saline (salt water) solution) into a child's veins ('fluid bolus therapy') and support for breathing and heart function. This study is looking at refining the fluid bolus therapy part of this package by exploring what the best amount of fluid to give in the earliest stages of treatment is. In order to explore this, the study will monitor children to find out if giving less fluid per bolus to children with symptoms of a septic shock is better than giving a higher amount of fluid, as currently recommended. The aim of this study is to conduct a small version of the study to find out how feasible the study methods are and to find out if it is possible to recruit enough children to take part.

Who can participate?
Children under 16 years of age who are showing signs of septic shock, their parents or legal guardians, and hospital research teams.

What does the study involve?
In the first part of this study, children are randomly allocated to one of two groups. Those in the first group receive the current recommended bolus (dose) fluid therapy, of 20 ml/kg (maximum 1000 ml per bolus) every 15 minutes for four hours, until the signs of shock have gone or there are signs of fluid overload (a condition where there is too much fluid in the blood). Those in the second group receive smaller boluses of 10 ml/kg (maximum 500 ml per bolus) according to the same schedule. The type of fluids and other treatments given are left up to the medical team to decide. For both groups, the amount of fluid given to the children is recorded. In the second part of the study, parents/legal guardians of children participating in the first part of the study complete a number of questionnaires and telephone interviews to find out their views on the study process. Three focus groups with the hospital research teams are also held to explore

their experiences of the study processes and consenting parents/legal representatives to the first part of the study.

What are the possible benefits and risks of participating?
It is not known whether there will be any additional benefits involved with participating in this study, however this study will help to improve the future treatment of children with septic shock. There are no notable risks involved with taking part.

Where is the study run from?
Thirteen NHS children's hospitals in England (UK)

When is the study starting and how long is it expected to run for?
December 2015 to April 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr David Inwald (scientific)
2. Ms Ruth Canter (public) (ruth.canter@icnarc.org)

Study website
https://www.icnarc.org/Our-Research/Studies/Fish/About

Contact information

Type(s)
Scientific

Contact name
Dr David Inwald

Contact details
Paediatric Intensive Care Unit
Queen Elizabeth The Queen Mother (QEQM) Wing
St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY

Type(s)
Public

Contact name
Ms Ruth Canter

Contact details
ICNARC CTU
Napier House
24 High Holborn

London
United Kingdom
WC1V 6AZ
+44 (0)207 269 9277
ruth.canter@icnarc.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16SM3292

Study information

Scientific Title
External pilot study of the Fluids in Shock (FiSh) trial

Acronym
FiSh Pilot Study

Study objectives
The aim of this study is to explore and test important key parameters needed to inform the design and ensure the successful conduct of the FiSh trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Stanmore Research Ethics Committee, 14/06/2016, ref: 16/LO/0854

Study design
Mixed methods:
1. Multicentre, pragmatic, open, pilot randomised controlled trial
2. Qualitative questionnaires, interviews and focus groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Sepsis/Septic shock

Interventions
Patients are randomised 1:1 using sealed opaque envelopes available at each site.

Intervention: Restrictive bolus fluid resuscitation of 10 ml/kg (maximum 500 ml per bolus)
Control: Current recommended bolus fluid resuscitation of 20 ml/kg (maximum 1000 ml per bolus)

Fluids to be delivered every 15 minutes for four hours, until clinical signs of shock has resolved or there are signs of fluid overload. Type of fluid and all other treatments are at the discretion of the treating clinician.

Intervention Type
Other

Primary outcome measure
Feasibility of the intervention processes is determined by the evaluation of all the secondary outcomes at the end of the study, including a recommendation, or not, to continue to a larger trial.

Secondary outcome measures
1. Eligibility rate is measured using the proportion of eligible patients randomised, as recorded on the screening and enrolment log at baseline
2. Recruitment rate is measured using the number of patients randomised per site per month, as recorded on the enrolment log and study database at baseline
3. Proportion of parents/guardians refusing deferred consent is measured using data recorded on the enrolment log and study database at hospital discharge or end of study (dependent upon timing of approach)
4. Proportion of fluid boluses delivered at correct volume and time during the intervention period is measured using data recorded on patient medical notes and the study database between randomisation and four hours post-randomisation
5. Total volume of fluid received during the intervention period is measured using data recorded on patient medical notes and the study database between randomisation and four hours post-randomisation
6. Proportion of complete data for each outcome measure is measured using data recorded on patient medical notes, the study database and linkage with routine data sources between randomisation and 30 days post-randomisation
7. Time taken for data collection and entry is measured using data from feedback from site staff during focus groups at the end of the study
8. Proportion of required data able to be linked to routine sources is measured using routine sources specification at the end of the study
9. Adverse events are measured using data recorded on patient medical notes and the study database between randomisation and 30 days post-randomisation

Overall study start date
01/12/2015

Completion date
30/04/2017

Eligibility

Key inclusion criteria
Pilot RCT:
Children:
1. Age greater than or equal to 37 weeks (corrected gestational age) and less than 16 years
2. Clinical suspicion of infection
3. Clinical signs of shock after receipt of 20 ml/kg of bolus fluid
4. Recruitment and randomisation to take place while child is in an acute assessment area (e.g. emergency department, paediatric assessment unit (PAU))

Observational component:
Parent/Guardian inclusion criteria (questionnaire component):
Parent/Guardians who were approached for consent prior to hospital discharge

Parent/Guardian inclusion criteria (telephone interview component):
Parent/Guardians who were approached for consent

Site research staff:
Site research staff who are involved in screening, recruiting, randomising and consenting during the pilot RCT.

Participant type(s)
Mixed

Age group
Child

Lower age limit
37 Weeks

Upper age limit
16 Years

Sex
Both

Target number of participants
108

Total final enrolment
75

Key exclusion criteria

Pilot RCT:
Children:
1. Prior receipt of more than 20 ml/kg of bolus fluid
2. Conditions in which bolus fluid resuscitation should be curtailed (e.g. raised intracranial pressure, diabetic ketoacidosis, known/suspected myocarditis/cardiomyopathy)
3. Full active resuscitation not within current goals of care

Observational component:
Parent/Guardian exclusion criteria (questionnaire and telephone interview):
Parents/Guardians who do not speak English.

Date of first enrolment
13/07/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Bristol Royal Hospital for Children
Paul O'Gorman Building
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Chelsea and Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Watford General Hospital
Vicarage Road
Watford
London
United Kingdom
WD18 0HB

Study participating centre
Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Study participating centre

Musgrove Park Hospital
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Sponsor information

Organisation
Imperial College Heathcare NHS Trust

Sponsor details
Joint Research Compliance Office
5th Floor, Laboratory Block
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF
+44 (0)203 311 0212
jrco@imperial.ac.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A comprehensive report recommending the continuation, or not, to the full FiSh trial will be submitted to the NIHR HTA programme for publication in Health Technology Assessment. The findings from both the feasibility and the external pilot study will be widely disseminated and

published in appropriate, peer-reviewed, scientific journals and, if appropriate, relevant professional journals within one year of the overall study end date.

Following initial presentation of the results to the collaborating sites, the results will be presented at national and international conferences/meetings. The results of the combined feasibility and pilot study will be disseminated to families (children and their parents/guardians) via the Clinical Studies Group for Children (Anaesthesia, Pain, Intensive Care and Cardiology), facilitated by clinical co-investigators who sit on the group, and via the Young Person's Advisory Group.

Intention to publish date
30/04/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results in Health Technology Assessment journal	01/09/2018		Yes	No
Results article	results	01/05/2019	24/01/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	For use in feasibility study interviews		18/09/2023	No	Yes
Results article	Qualitative interview study results	28/08/2017	18/09/2023	Yes	No