

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

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| Submission date 03/08/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 11/08/2016 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 18/09/2023 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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)

Contact information

Type(s)

Scientific

Contact name

Dr David Inwald

Contact details

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Public

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Ms Ruth Canter

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

37 weeks

Upper age limit

16 years

Sex

All

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

United Kingdom

England

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
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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 Healthcare NHS Trust

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

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 |
| Results article | Qualitative interview study results | 28/08/2017 | 18/09/2023 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | For use in feasibility study interviews | | 18/09/2023 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |