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Early recognition and management of maternal sepsis in Pakistan

Submission date
27/10/2021

Recruitment status
No longer recruiting

Registration date
04/11/2021

Overall study status
Completed

Last Edited
31/07/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Maternal sepsis is a severe bacterial infection (usually of the womb) that can occur in pregnant women or in the days following childbirth. The World Health Organization estimates suggests that globally, maternal sepsis accounts for about one-tenth of the maternal deaths around the time of childbirth and is the third most common cause of maternal death. Whilst the maternal death rate related to sepsis has decreased considerably in high-income countries accounting for 2.1% of the total maternal deaths, the numbers are still high in the lower-income countries accounting for up to 15.1% of maternal deaths annually. However, more recent WHO estimates that were focused specifically on understanding better the contribution of maternal infection to adverse outcomes suggested that up to half of all maternal deaths were actually infection-related.
The FAST-M intervention was implemented in districts of Malawi to evaluate the feasibility of early identification and management of maternal sepsis and demonstrated significant improvements in maternal sepsis care in Malawi. The components included 1) the Maternal Early Obstetric Warning System (MEOWS) chart and FAST-M decision tool, 2) the FAST-M treatment bundle and 3) the FAST-M implementation programme which consisted of the following: training programme, sepsis champions, task shifting, performance dashboards and data feedback to promote systems-level change. Therefore, this study aims to determine whether it is feasible to introduce a complex intervention (including a bundled approach) for maternal sepsis care in Pakistan.

Who can participate?
Women who are pregnant or within 6 weeks of miscarriage, termination of pregnancy or delivery, and are receiving inpatient healthcare

What does the study involve?
After a period of 2 months when standard care is assessed in all the three obstetrics and gynecology units of the study site, the intervention will be introduced for up to 4 months. All units will receive three components of the intervention for the same duration of time each. The components include a modified early warning score and a decision tool to enable recognition of

maternal sepsis; a treatment bundle for those with suspected maternal sepsis; and a teaching programme and implementation strategy to educate healthcare practitioners on how to use the early warning scores, decision tool and treatment bundle to manage maternal sepsis.

What are the possible benefits and risks of participating?
Individual components of this care bundle have been shown to improve quality of care. However, fluid resuscitation (replacing lost bodily fluid) if not managed appropriately can cause volume overload and subsequent pulmonary oedema (fluid accumulation in the lungs). This is a particular concern in patients with pre-eclampsia (high blood pressure). Clear teaching and guidance regarding fluid resuscitation will be provided during the training programme. When fluid resuscitating patients with suspected maternal sepsis, the decision regarding the rate of fluid administration will be made by the responsible clinician based on clinical examination findings and ongoing monitoring. The study has been designed and resourced with the aim of preventing any such effects, but the researchers will actively monitor for any such adverse impacts on other aspects of care within the study site.

Where is the study run from?
The study will be conducted at Liaquat University of Medical Health Sciences (LUMHS), which is a public sector tertiary hospital located in the Hyderabad district of Pakistan. LUMHS has three Obstetrics and Gynecology units where the study will be carried out.

When is the study starting and how long is it expected to run for?
February 2019 to February 2022

Who is funding the study?
1. University of Birmingham (UK)
2. University of Liverpool (UK)
3. National Institute for Health Research (UK)
4. Bill and Melinda Gates Foundation (USA)

Who is the main contact?
1. Dr Sheikh Irfan Ahmed (public), sheikh.irfan@aku.edu
2. Prof David Lissauer (scientific), David.Lissauer@liverpool.ac.uk

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2.5 07/08/2019

Study information

Scientific Title
Evaluation of the FAST-M maternal sepsis bundle in Pakistan: a feasibility study

Acronym
FAST-M (PK)

Study objectives
Introducing the FAST-M intervention into the healthcare system of Pakistan is feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/12/2019, Aga Khan University Ethical Review Committee (Stadium Road, PO Box 3500, Karachi 74800, Pakistan; +92 (0)21 3493 0051 Ext: 4988/2445; erc.pakistan@aku.edu), ref: 2019-2061-7102

Study design
Mixed method study with a before and after design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Maternal sepsis

Interventions
The study will be conducted in two phases. In the first phase (qualitative) the researchers will adapt the FAST-M bundle care tools for the local context. In the second phase, they will evaluate the feasibility of the FAST-M intervention.

Component 1: introduction of a modified early obstetric warning score to enable the observation of patients to be recorded and also the FAST-M decision tool to enable recognition of maternal sepsis
Component 2: introduction of the FAST-M treatment bundle for those with suspected maternal sepsis
Component 3: introduction of a teaching programme and implementation strategy educating healthcare practitioners on how to use the early warning scores, decision tool and treatment bundle to manage maternal sepsis
Control: standard care

After a baseline phase of 2 months, during which standard care will be assessed in all obstetrics and gynecology (OBGYN) units at the study site, the intervention phase will commence in all OBGYN units and will run for up to 4 months (or until saturation - whichever takes place first). All units will get all three components of the intervention for the same duration of time each.

Intervention Type
Behavioural

Primary outcome measure
Collected using CRFs every 2 weeks throughout the intervention phase:
1. The proportion of patients admitted with features of sepsis who received appropriate monitoring (full set of vital sign measurements on admission recorded on MEOWS chart)
2. The proportion of women with suspected maternal sepsis received antibiotics within 1 hour (if required)
3. The proportion of women with suspected maternal sepsis receiving the FAST-M treatment bundle (including each bundle component) within 1 hour of identification of sepsis
4. One focus group will be conducted before the initiation of the study to adapt the tools and identify implementation approaches
5. A second focus group will be conducted at the end of the study as a summative evaluation of the study to identify perceptions about the success of implementation

Secondary outcome measures
Collected using CRFs every 2 weeks throughout the intervention phase:
1. The proportion of women with suspected maternal sepsis referred to clinical decision-maker on the basis of abnormal vital signs records
2. The proportion of women with suspected maternal sepsis receiving a clinical review by a senior clinical decision-maker following their diagnosis

Overall study start date
04/02/2019

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Women who are pregnant or within 6 weeks of miscarriage, termination of pregnancy or delivery
2. Receiving inpatient health care

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
As this is a feasibility trial there is no target number of participants required for the study as this study is looking at whether introducing an intervention in this setting is possible. However, assuming baseline compliance is less than 10% grounded on observations from FAST-M study in Malawi, to detect an increase in compliance to 20%, with an alpha of 0.05, the study will require the observation of 199 participants in each phase to achieve a power of 80%.

Total final enrolment
400

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
20/10/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Pakistan

Study participating centre
Liaquat University of Medical and Health Sciences
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/015jxh185

Funder(s)

Funder type
University/education

Funder Name
University of Birmingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
University of Liverpool

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan

1. Results will be disseminated to all collaborators through quarterly interim reports and meetings with the University of Birmingham team
2. The study team plans the dissemination of results not only to the academic community but internationally through the WHO, FIGO and other non-governmental organizations (NGOs)
3. Planned publication in a high impact peer-reviewed journal around 1 year after the overall trial date end date

Intention to publish date

31/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			01/11/2021	No	No
Interim results article	Results of qualitative exploratory study	09/09/2022	24/01/2023	Yes	No
Results article		30/07/2023	31/07/2023	Yes	No