

Wearable device to Observe Movements of your Baby (WOMB) study

Submission date 28/04/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/09/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Fetal movements are reassuring for fetal health. It can be difficult for some women to appreciate fetal movements and this can lead to unnecessary medical intervention. We propose to test a thin, flexible textile-like sensor (which is conformable, breathable, and washable) embedded within a wearable garment, KYMIRA will create a solution that is easier and more comfortable for longer-term monitoring. Moreover, the wearable will be fully washable, enabling better hygiene and potentially allowing 24-hour monitoring.

We aim to correlate objectively measured fetal movements with those detected by the device via real-time imaging of the moving fetus using ultrasound. The study intervention will involve four ultrasound scans lasting 20 min during which fetal movements will be recorded by the scan operator. The fabric device will also be worn on the mother's abdomen and will also be recording movement. The mother will also have a button to press when she feels movements. The four scans will happen at 2-week intervals from 32 weeks of pregnancy.

Other studies have looked into various devices. Often these are bulky, non-washable and require hospital visits. Some use methods, such as picking up the acoustics of fetal movement. Our device works by using a piezoelectric fabric which essentially generates a tiny voltage when the material is bent or stretched.

Who can participate?

Women aged 18-40 who are pregnant with one baby and have a body mass index (BMI) between 18-30.

What does the study involve?

Participants will be asked to attend 4 extra ultrasound scans in the later part of their pregnancy. A fabric device will be worn which is designed to pick up movements of the fetus. Both the mother, the device, and the scan operator will be assessing fetal movements.

What are the possible risks and benefits?

Taking part in the trial is not going to be directly beneficial to participants, although they will get to see their baby on scan a few extra times. The disadvantage of taking part in the trial is that

participants will be asked to come into the hospital for four extra scans between 32 and 38 weeks of pregnancy. This will take time out of their day.

Where is the study run from?

Cambridge University Hospitals NHS Foundation Trust (UK) and University Hospitals of Leicester (UK)

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

From June 2021 to December 2025

Who is funding the study?

Kymira (UK) through an Innovate UK grant

Who is the main contact?

Dr Suzi Dunkerton

Suzanna.dunkerton@uhl-tr.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Dr Suzanna Dunkerton

ORCID ID

<https://orcid.org/0000-0001-9258-0804>

Contact details

Consultant in Fetomaternal medicine

Obstetric secretary's

Kensington building

Leicester Royal Infirmary

Infirmary square

Leicester

United Kingdom

LE15WW

+44 (0)1162587770

Suzanna.dunkerton@uhl-tr.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2021-002341-15

Integrated Research Application System (IRAS)

288119

Protocol serial number

WOMB01, IRAS 288119

Study information

Scientific Title

Wearable device to Observe Movements of your Baby (WOMB) study

Acronym

WOMB

Study objectives

To determine the effectiveness of the wearable device in detecting fetal movements, as identified by the operator scanning, compared with those detected by the pregnant women.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 18/04/2023, Health and Social Care Research Ethics Committee A (HSC REC A) (ORECNI, Lissure Industrial Estate West, 5 Rathdown Walk, Lisburn, BT282RF, United Kingdom; +44 (0)28 9536 1400; RECA@hscni.net), ref: 21/NI/0115

Study design

Multicentre single-arm non-randomized study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Fetal movement

Interventions

Pregnant women in their third trimester with a singleton pregnancy will test a device designed to pick up fetal movements. The WOMB device will be worn for 20 min by the pregnant participant in the third trimester during ultrasound scans at weeks 32, 34, 36, and 38 of pregnancy. A scan operator and the mother will also be determining when the fetus is moving. The results will then be correlated with what the wearable device has picked up.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fabric device

Primary outcome(s)

Effectiveness of the wearable device in detecting fetal movements, as identified by the operator scanning, compared with those detected by the pregnant women measured using data from the wearable device, ultrasound scan, and maternal report during the 20 min scan at weeks 32, 34, 36, and 38 of pregnancy

Key secondary outcome(s)

1. Proportion of movements detected by the device and by the pregnant women that are true-positives, that is those that are also identified by the scan operator (i.e., their positive-predictive value rates) measured using data from the wearable device, ultrasound scan, and maternal report during the 20 min scan at weeks 32, 34, 36, and 38 of pregnancy
2. Acceptability of wearing the device as self-reported by the women in a bespoke end of study questionnaire

Completion date

01/12/2025

Eligibility

Key inclusion criteria

1. Willing and able to give informed consent for participation in the study
2. Aged between 18 and 40 years
3. ≤ 32 weeks gestation
4. Body mass index (BMI) between 18 and 30 at booking
5. Able (in the Investigator's opinion) and willing to comply with all study requirements
6. Willing to allow their General Practitioner and Obstetric Consultant, to be notified of participation in the study
7. Singleton pregnancy

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Any concerns have been raised at previous scans, although if the scan has been reviewed by fetal medicine and deemed there are no concerns then the patient can be included
2. Delivery planned prior to 39 weeks at recruitment.
3. Multiple pregnancy

Date of first enrolment

01/10/2024

Date of final enrolment

01/10/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cambridge University NHS Foundation Trust

Robinson Way

Cambridge

United Kingdom

CB2 0QQ

Study participating centre

University Hospitals of Leicester

Infirmery Square

Leicester

United Kingdom

LE15WW

Sponsor information

Organisation

Kymira

Funder(s)

Funder type

Industry

Funder Name

Kymira

Results and Publications

Individual participant data (IPD) sharing plan

Data collected from the device that is worn by participants will be kept by Kymira and are not expected to be made available. The analysed data collected during this study will be included in the subsequent results publication.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	12/05/2016	27/07/2021	No	Yes
Protocol file	version 2	12/04/2021	27/07/2021	No	No