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The lactate in pregnancy study

Submission date
16/08/2023

Recruitment status
No longer recruiting

Registration date
12/09/2023

Overall study status
Completed

Last Edited
23/05/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Lactate is an important marker which is produced naturally by the body during exercise. It increases when a person is unwell, for example, with a severe infection. It is currently used during pregnancy if doctors suspect a bad infection or if a woman/birthing person has lost a lot of blood around the time of birth. However, the blood level of lactate may be difficult to understand during labour as labour is itself an exercise, and so can probably raise this level. This is why it is important to understand more about lactate levels in pregnant women/birthing people. Currently, lactate can only be measured through blood tests, which means it is difficult to get a clear understanding of normal lactate levels during labour. Imperial College London has developed a new patch to measure lactate. It works by using a sensor placed on the surface of the skin. Similar methods are used to monitor blood sugar levels in diabetic mothers, and this is seen as comfortable to wear by women/birthing people. The patch is painless and does not involve any blood testing. The patch can continuously measure the lactate levels in your skin and send the information to a computer. The patch has been shown to be effective and well-tolerated in a recent study of non-pregnant individuals. The first part of this study aims to use the patch in healthy pregnant women/birthing people to measure the lactate produced during, and after a period of gentle exercise and compare this with the normal ways of measuring lactate (i.e. blood tests) and understand their experience of wearing it, this study will last for 3 hours. If this works, the study will move to the second part to investigate the best place to wear the patch (study 2), if the patch works for 6 and 12 hours (study 3), and also to understand if the patch can be stored in fridge (study 4) and continue to work several months later.

Who can participate?
Study 1: Healthy pregnant women with no existing health conditions or pregnancy complications who are able to exercise for 30 minutes with normal fetal movements on the day of participation.
Study 2-4: Healthy non-pregnant volunteers

What does the study involve?
Study 1: The researchers will place the patch on the participant's arm by pressing it gently on the skin and fixing it with a bandage. They will also put a drip (cannula) into their vein to take samples of blood during the study. Once set up, participants sit and relax for 30-60 minutes and the researchers take two blood samples from the cannula during this time. Then participants walk on the spot/cycle/step for 30 minutes as fast as they feel is comfortable. During this time, blood will be sampled every 5 minutes. After this the participants rest. The study will end about

an hour after the start of exercising. The drip and patch will be removed and participants will be asked to fill out a short questionnaire. They will be asked for a photograph of the skin where the patch has been placed.
Study 2: similar to study 1; however, the participant wears the device in 2 places at the same time.
Study 3: similar to study 1, except participants will be asked to exercise at the beginning and end of the 6 or 12-hour time period.
Study 4: Similar to study 2, except it will take place at different durations after the device is made and sterilised.

What are the possible benefits and risks of participating?
All procedures and equipment used in this study have been shown to be safe in previous studies. The researchers do not expect any significant side effects during or after the study.
For the patch, the main possible side effects are skin irritation or discomfort. It has been used before for 24 hours without pain or discomfort. A drip will be placed in the arm to take blood during the study. This might result in bruising of the skin although it will not cause any other problems – the bruising typically resolves in less than 1 week.
The exercise will be done by walking on the spot/stepping onto a step/cycling. The total length of exercise is 30 minutes. Participants can stop if they feel unwell, unusual or have period-like pain.

Where is the study run from?
The study is run by University of Liverpool Researchers physically located in the University of Liverpool research facility at the Harris Centre for Women's Health Research (UK)

When is the study starting and how long is it expected to run for?
June 2023 to December 2025

Who is funding the Study?
The Wellcome-University of Liverpool Institutional Translational Partnership (ITPA) Translational Research Access Programme (TRAP) (UK)

Who is the main contact?
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Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
332026

Protocol serial number
UoL001792

Study information

Scientific Title
Minimally-invasive biosensor monitoring of lactate in healthy pregnancies: a proof of concept study

Acronym
LIP

Study objectives
Proof of concept study for continuously measuring lactate in healthy pregnant women.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/08/2023, West of Scotland REC 4 (Research Ethics, Ward 11 Dykebar Hospital, Paisley, PA2 7DE, United Kingdom; +44 (0)1413140213; WoSREC4@ggc.scot.nhs.uk), ref: 23/WS/0121

Primary study design
Observational

Study design
Proof of concept study

Study type(s)
Other

Health condition(s) or problem(s) studied
Pregnancy

Interventions
Continuous measurement of lactate levels using a microneedle biosensor compared to blood lactate levels to prove the concept for using the device during pregnancy.

The researchers will place the patch on the participant's arm by pressing it gently on the skin and fixing it with a bandage. They will also put a drip (cannula) into their vein to take samples of blood during the study.
Once set up, participants sit and relax for 30-60 minutes and the researchers take two blood samples from the cannula during this time. Then participants walk on the spot/cycle/step for 30 minutes as fast as they feel is comfortable. During this time, blood will be sampled every 5 minutes. After this the participants rest.
The study will end about an hour after the start of exercising. The drip and patch will be removed and participants will be asked to fill out a short questionnaire. They will be asked for a photograph of the skin where the patch has been placed.

Intervention Type
Device

Phase
Phase 0

Drug/device/biological/vaccine name(s)
Minimally-invasive lactate biosensor

Primary outcome(s)
Current primary outcome measures as of 23/04/2025:
1. Continuous lactate measurement using the LIP sensor throughout the duration of the study
2. Venous lactate samples measured using a colourimetric assay at baseline, throughout the duration of the exercise and in the post-exercise rest period

Previous primary outcome measures:
1. Continuous lactate measurement using the LIP sensor throughout the 3-hour duration of the study
2. Venous lactate samples measured using a colourimetric assay at baseline, throughout the duration of the exercise and in the post-exercise rest period

Key secondary outcome(s)
Current secondary outcome measures as of 23/05/2025:
1. Feedback on the experience of wearing the device, measured using a questionnaire immediately after the device is removed
2. Whether the device performs similarly on different parts of the body by comparing the lactate curves throughout the experiment
3. Whether the device can be stored for weeks/months by examining the lactate curves that are produced at several weeks/months after the device is produced

Previous secondary outcome measures:
Feedback on the experience of wearing the device, measured using a questionnaire immediately after the device is removed

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 23/04/2025:
Study 1:
1. Consenting pregnant adults ≥18 years old
2. Healthy with no previously diagnosed medical condition from a medical practitioner
3. Report no pregnancy complications
4. Can be taking prophylactic drugs in pregnancy for example aspirin for low PAPP-A and folic acid and other pregnancy vitamins
5. Report they are able to exercise gently for 30 minutes and do similar exercise routinely
6. Normal fetal movements on the day of participation

Study 2:
1. Consenting adults ≥ 18 years old
2. Healthy with no previously diagnosed medical condition from a medical practitioner
3. Report they are able to exercise for 60 minutes, and do similar exercise routinely

Previous participant inclusion criteria:
1. Consenting pregnant adults ≥18 years old
2. Healthy with no previously diagnosed medical condition from a medical practitioner
3. Report no pregnancy complications
4. Can be taking prophylactic drugs in pregnancy for example aspirin for low PAPP-A and folic acid and other pregnancy vitamins
5. Report they are able to exercise gently for 30 minutes and do similar exercise routinely
6. Normal fetal movements on the day of participation

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Key exclusion criteria
1. Active inflammatory skin condition such as eczema or dermatitis
2. Active soft tissue infection or infection at any site
3. Known hypersensitivity to any microneedle component/cannula dressing or plasters
4. Presence of any implantable electronic devices such as a pacemaker or stimulators

Date of first enrolment
01/10/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

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Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research organisation

Funder Name
The Wellcome-University of Liverpool Institutional Translational Partnership (ITPA) Translational Research Access Programme (TRAP)

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date