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The lactate in pregnancy study

Submission date	Recruitment status	[X] Prospectively registered
16/08/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2024	Pregnancy and Childbirth	[X] Record updated in last year

Plain English Summary

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 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 to 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 aim of this study is 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.

Who can participate?
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.

What does the study involve?
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.

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 2024

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?
Dr Abi Merriel, nimble@liverpool.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Abi Merriel

ORCID ID
http://orcid.org/0000-0003-0352-2106

Contact details
Centre for Women's Health Research
Department of Women's and Children's Health
University of Liverpool
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS
+44 (0)151795 9562
abi.merriel@liverpool.ac.uk

Type(s)
Scientific

Contact name
Dr Abi Merriel

Contact details
Centre for Women’s Health Research
Department of Women’s and Children’s Health
University of Liverpool
Liverpool Women’s Hospital
Crown Street
LIverpool
United Kingdom
L8 7SS
+44 (0)151 795 9562
abi.merriel@liverpool.ac.uk

Type(s)
Public

Contact name
Mrs Tracey Ricketts

Contact details
Centre for Women’s Health Research
Department of Women’s and Children’s Health
University of Liverpool
Liverpool Women’s Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS
+44 (0)151 795 9562
nimble@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332026

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UoL001792, IRAS 332026

Study information

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

Acronym
LIP

Study hypothesis
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

Study design
Proof of concept study

Primary study design
Observational

Secondary study design
Proof of concept study

Study setting(s)
University/medical school/dental school

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Condition
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.

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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.
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Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase 0

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

Primary outcome measure
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

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

Overall study start date
01/06/2023

Overall study end date
31/12/2024

Eligibility

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

Age group

Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Target number of participants
10

Participant 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

Recruitment start date
01/10/2023

Recruitment end date
31/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
Centre for Women’s Health Research
Department of Women’s and Children’s Health
University of Liverpool
Liverpool Women’s Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool Womens Hospital

Crown Street
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
University of Liverpool

Sponsor details
Clinical Directorate
4th Floor Thompson Yates Building
Faculty of Health and Life Sciences
Liverpool
England
United Kingdom
L69 3GB
+44 (0)7717863747
sponsor@liverpool.ac.uk

Sponsor type
University/education

Website
http://www.liv.ac.uk/

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

Publication and dissemination plan

The researchers plan to produce a peer-reviewed publication and share the findings at conferences.

Intention to publish date
01/01/2025

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