

Are subjective pain scores related to facial muscle activity?

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| Submission date 04/06/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 10/07/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 13/12/2023 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

This study aims to discover if we can compare the pain felt by patients with a measurement of how their faces move. Facial movements will be assessed using muscle activity sensors worn like a pair of glasses/goggles that measure underlying muscle activity. Past studies show facial expression is sensitive to the intensity of pain. Laboratory studies looking at pain in volunteers suggest facial electromyography (EMG) to measure muscle activity could be a useful tool to determine the pain an individual is suffering. This may have particular relevance to patients where communication is limited such as patients with dementia.

Who can participate?

Patients aged 18 and over requiring hand surgery under local anaesthetic at the Queen Victoria Hospital

What does the study involve?

Whilst they are receiving the anaesthetic injection the participant's facial muscle response is recorded non-invasively using specialized goggles containing muscle sensors. Simultaneously the participant's experience of pain is recorded using a self-reported visual analogue score (VAS). Pain expectation is also considered, and anxiety traits and status are assessed before the intervention.

What are the possible benefits and risks of participating?

The results will further the scientific understanding of facial EMG responses and may benefit patients in the future who are unable to communicate with their clinicians. Furthermore patients are often keen to be involved in research as it gives them an opportunity to 'give back' to the healthcare service that cares for them. Participants may feel that completing questionnaires are laborious or intrusive. For this reason, the questionnaires used have been carefully selected to minimise the amount of time demanded of patients and in order to only address pertinent questions. During Patient and Public Involvement (PPI) consultation survey gathered for the purpose of the study patients were happy to have additional monitoring in place during their routine clinical procedure. A local anaesthetic injection is painful but is necessary for surgery to take place. The participants will not be subjected to any additional painful procedures.

Where is the study run from?
Queen Victoria Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2019 to June 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Julian Giles
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
A comparison of facial muscle responses with reported pain scores in patients undergoing a routine clinical procedure

Study objectives

The researchers intend to look at how the facial muscle activity readings measured during routine clinical care correlate with the participant's own reported real-time pain score during the procedure. They intend to use a visual analogue scale (VAS) pain score linked into a computer which will give a real-time self-reported pain score that they can then compare to the readings to that measured directly from the face. The VAS is a pain rating scale first used by Hayes and Patterson in 1921. It is the most widely used and validated scoring system in the subjective measurement of pain. It is based on self-reported measures of symptoms that are recorded with a single handwritten mark placed at one point along the length of a 10-cm line that represents a continuum between the two ends of the scale - "no pain" on the left end (0 cm) of the scale and the "worst pain" on the right end of the scale (10 cm). More recently digital methods using a sliding scale have superseded the paper version. These have been externally validated and are widely used in both experimental and clinical medicine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 18/11/2019:

Approved 12/06/2019, South Central - Oxford C - Research Ethics Committee (Level 3, Block B, Whitefriars Building, Lewins Mead, Bristol, BS1 2NT; Tel: +44 (0)207 1048 045; Email: nrescommittee.southcentral-oxfordc@nhs.net), ref: 19/SC/0274

Previous ethics approval:

Approval pending, South Central - Oxford C - Research Ethics Committee (Level 3, Block B, Whitefriars Building, Lewins Mead, Bristol, BS1 2NT; Tel: +44 (0)207 104 8290, +44 (0)207 104 8041; Email: nrescommittee.southcentral-oxfordc@nhs.net), ref: 19/SC/0274

Study design

Single-centre observational study

Primary study design

Observational

Secondary study design

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Measuring pain felt by patients with a measurement of how their faces move

Interventions

Patients receive a local anaesthetic injection before a planned hand operation. Whilst they are receiving the injection the facial muscle response is recorded non-invasively using specialized

goggles containing muscle sensors. The data received from the facial muscle sensors will be correlated against the self-reported pain scores using a real-time visual analogue scale for a time period including baseline, during local anaesthetic injection and post injection. Measuring facial muscle activity using electromyography can be cumbersome due to the need for electrodes coated with conductive gel, adhesive pads and multiple trailing cables. Therefore we will use a new sensor system that simplifies the data collection by incorporating the sensors into a single system worn on the face like a pair of glasses. Pain expectation will also be considered, as well as participant anxiety traits and status prior to intervention.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

emteqPRO facial mask

Primary outcome measure

1. The timing and magnitude of the muscle response from the peri-orbital muscles to the painful stimulus (a local anaesthetic injection to the finger), recorded non-invasively using specialized goggles containing muscle sensors at baseline, during painful stimulus and post stimulus
2. Pain measured using a visual analogue scale (VAS) pain score linked into a computer at baseline, during painful stimulus and post stimulus

Secondary outcome measures

1. The amplitude of peri-orbital facial muscle activity (Corrugator Supercilii + Orbicularis Oculi), recorded non-invasively using specialized goggles containing muscle sensors at baseline, during painful stimulus and post stimulus
2. Heart rate and heart rate variability, measured using sensors in the specialised goggles and using a continuous ECG recording at baseline, during painful stimulus and post stimulus

Overall study start date

30/06/2019

Completion date

31/01/2022

Eligibility

Key inclusion criteria

Patient:

1. Adult age 18+ with full capacity
2. ASA I (normal, healthy) and II (mild systemic disease; no functional limitation)
3. Fluent in English

Trauma/procedure:

1. Patients have received superficial trauma to the hand only
2. Patient is due to have examination and operation performed under local anaesthesia only
3. A digital ring block is planned for anaesthesia/analgesia during the procedure

4. No sedation/intravenous opioids are due to be administered
5. Oral analgesia via WHO analgesic ladder is permitted

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Total final enrolment

40

Key exclusion criteria

1. A history of chronic pain on long term opiates
2. A diagnosis of dementia/long-term memory impairment
3. Previous facial surgery (previous minor facial laceration suturing does not exclude)
4. Cosmetic facial procedures, e.g. botox injection or cosmetic "fillers"
5. Past history of facial neuromuscular disease eg Bell's palsy
6. Pregnant

Date of first enrolment

15/09/2020

Date of final enrolment

01/12/2021

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Queen Victoria Hospital

Holtye Road

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RH19 3DZ

Sponsor information

Organisation

Queen Victoria Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

www.qvh.nhs.uk

ROR

<https://ror.org/01ywpj09>

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

Publication and dissemination plan

Planned publication in a high impact peer-reviewed journal – intend to publish Summer 2021.

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |
| Abstract results | International Association for the Study of Pain (IASP) 2022 World Congress on Pain, 19-23 September 2022, Toronto, Canada | 19/09/2022 | 12/12/2023 | No | No |