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Are subjective pain scores related to facial muscle activity?

Submission date
04/06/2019

Recruitment status
No longer recruiting

Registration date
10/07/2019

Overall study status
Completed

Last Edited
13/12/2023

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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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Sponsor information

Organisation
Queen Victoria Hospital

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Sponsor type
Hospital/treatment centre

Website
www.qvh.nhs.uk

ROR
https://ror.org/01ywpxj09

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