Is buprenorphine patch more effective than standard oral medication in the management of post-tonsillectomy pain: a study on how people cope with the pain following the removal of tonsils

Submission date	Recruitment status	Prospectively registered
24/10/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
16/04/2008	Completed	[X] Results
Last Edited 21/04/2020	Condition category Signs and Symptoms	[] Individual participant data

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Viswanath Puranik

Contact details

North West Wales NHS Trust ENT Department Ysbyty Gwynedd Bangor United Kingdom LL57 2PW

Additional identifiers

EudraCT/CTIS number 2007-006117-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Puranik 07/03/23

Study information

Scientific Title

PATCH Trial: Post-tonsillectomy Analgesia with buprenorphine Transdermal patCH: a prospective, randomised, phase IV, open label clinical trial to study the therapeutic use of buprenorphine 20 mg (Transtec®) matrix transdermal patch in the management of post-tonsillectomy pain in adults

Acronym

PATCH Trial

Study objectives

To establish whether post-tonsillectomy analgesia using a transdermal patch has benefits over currently used oral analgesia, by comparatively measuring the clinical efficacy, the effective and perceived pain control, and the rate at which complications and adverse effects occur.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North East Wales Research Ethics Committee (REC), 31/01/2008, ref: 07/WNo03/23

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details provided in the interventions field to request a patient information sheet

Health condition(s) or problem(s) studied

Post-tonsillectomy pain

Interventions

Arm A (interventional): will receive a 12 day supply of buprenorphine 20 mg (35 mg/h) (Transtec®) matrix transdermal patches (a total of four patches). Patients are required to replace the transdermal patch every three days.

Arm B (control): will receive a 12-day supply of codeine phosphate 30 mg/ paracetamol 500 mg (30/500/Solpadol®). Patients are required to take two tablets every four hours (p.r.n).

Total duration of treatment is 12 days. Final assessment and all data collected at day 10 (outpatient clinic), for both arms, no other follow-up.

Please use the following contact details to request a patient information sheet: Dr. Rossela O. Stoicescu
Clinical Governance Officer (R&D Manager/Ethics Co-ordinator)
North Wales Clinical School - Clinical Academic Office
North West Wales NHS Trust
Ysbyty Gwynedd
Bangor, Gwynedd
LL57 2PW

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Buprenorphine (Transtec®), codeine phosphate hemihydrate, paracetamol (Solpadol®)

Primary outcome measure

- 1. Clinical efficacy: the buprenorphine: creatinine ratio
- 2. Perceived pain: measurements on the Visual Analogue Scale (VAS)
- 3. Coping strategies: the compounded prevalent strategy

All outcomes will be measured at day 10 of the intervention.

Secondary outcome measures

- 1. Use (dose/frequency) of rescue medication
- 2. Readmission rate
- 3. Post-operative haemorrhage rate

All outcomes will be measured at day 10 of the intervention.

Overall study start date

15/11/2007

Completion date

30/10/2009

Eligibility

Key inclusion criteria

Patients undergoing tonsillectomy, who meet the following criteria:

- 1. Aged 18 to 50 years old, either sex
- 2. American Society of Anaesthesiologists (ASA) grade I and II: healthy patient, mild systemic disease with no functional limitation (e.g., well controlled hypertension [HTA])

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150 in each arm, 300 in total

Total final enrolment

133

Key exclusion criteria

- 1. Age less than 18 or over 50 years
- 2. ASA grade III severe systemic disease with definite functional limitation (e.g., unstable angina)
- 3. Any condition in which the respiratory centre and function are severely impaired or may become so
- 4. Asthmatic and allergic to non-steroidal anti-inflammatory drugs (NSAIDS)
- 5. Hypotension
- 6. Pregnancy and lactation
- 7. Recent head injury
- 8. Known hypersensitivity towards the active substance buprenorphine or to any of the excipients
- 9. Opioid-dependent patients, or patients in narcotic withdrawal treatment
- 9. Patients who are receiving monoamine oxidase (MAO) inhibitors or have taken them within the last two weeks
- 10. Patients suffering from myasthenia gravis
- 11. Patients suffering from delirium tremens or acute alcohol intoxication
- 12. Convulsive disorders

Date of first enrolment

15/11/2007

Date of final enrolment

30/10/2009

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre North West Wales NHS Trust

Bangor United Kingdom LL57 2PW

Sponsor information

Organisation

North West Wales NHS Trust (UK)

Sponsor details

c/o Dr. P. Birch Ysbyty Gwynedd Bangor Wales United Kingdom LL57 2PW

Sponsor type

Hospital/treatment centre

Website

http://www.northwestwales.org/

ROR

https://ror.org/04a496k07

Funder(s)

Funder type

Government

Funder Name

North West Wales NHS Trust (UK) - Pathology Research Fund

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Basic results21/04/2020NoNo