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 No longer recruiting	Prospectively registered			
24/10/2007		☐ 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

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Additional identifiers

Clinical Trials Information System (CTIS) 2007-006117-16

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 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.

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

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)

ROR

https://ror.org/04a496k07

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/04/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes