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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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)
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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
All

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