ISRCTN10393098 https://doi.org/10.1186/ISRCTN10393098

Comparing the effectiveness of post-burn itchy skin treatment with cetirizine or gabapentin

Submission date
21/05/2022

Recruitment status
No longer recruiting

Registration date
30/05/2022

Overall study status
Completed

Last Edited
09/02/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The majority of burn patients suffer from itch (pruritus) during the time of healing and this is a very difficult symptom to treat. The available treatment options have largely not been efficient in treating this disturbing condition. At the Burn Unit of the Korle-Bu Teaching Hospital, patients with post burn itch are often given cetirizine, an antihistamine. This treatment is largely unsatisfactory as many patients do not get relief. New agents for treatment are now available and there is a need to evaluate their efficacy. The aim of this study is to compare the effectiveness cetirizine, gabapentin and a combination of cetirizine and gabapentin in the treatment of pruritus in burn patients. The study will thus score which of the drugs is more effective and will subsequently influence practice in the Unit.

Who can participate?
The study involves burn patients.

What does the study involve?
Participants were asked to provide some personal information such as age, and also, provide information about their condition. They were assigned a random number and were recruited into one of the three arms of the study. The intensity of their itch was scored using a scale. They were also asked a series of questions to assess whether they had sleep disturbance as a result of the itch. Depending on the assigned group, they were given Cetirizine, Gabapentin or a combination of these two drugs. They were reviewed at regular intervals to evaluate the effect of the drug on your itch and to take note of any side effects of the drug. The quality of care was the same for all participants

What are the possible benefits and risks of participating?
There are no direct benefits for participation. However, your participation will contribute to building knowledge on the research topic and ultimately improve management and treatment of post-burn itch.
There are no foreseeable risks associated with participating in this study beyond the documented side effects of the drugs to be administered

Where is the study run from?
National Reconstructive Plastic surgery and Burn Centre (Ghana)

When is the study starting and how long is it expected to run for?
December 2016 to March 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Elliott Arko-Boham, BArko-Boham@ug.edu.gh, sojiar20@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Elliott Arko-Boham

ORCID ID
https://orcid.org/0000-0001-6429-2186

Contact details
National Reconstructive Plastic surgery and Burn Centre
Korle-Bu Teaching Hospital
P.O Box KB 76
Accra
Ghana
+233
+233 206 301 118
BArko-Boham@ug.edu.gh

Additional identifiers

Protocol serial number
CHS-Et/M.9-P4.3/2016/2017]

Study information

Scientific Title
Effectiveness of post-burn pruritus treatment with cetirizine and gabapentin – a comparative study

Study objectives
The effectiveness of gabapentin is greater than the effectiveness of cetirizine against itching in post-burn treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/04/2017, Ethical and Protocol Review Committee (College of Health Sciences of the University of Ghana, Accra, Ghana; +233 (0) 302 665103; administration@chs.edu.gh), ref: CHS-Et/M.9 - P 4.3/2016-2017

Study design
Interventional randomized double-blind controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of pruritus in post-burn patients

Interventions
The study was conducted on patients with burns involving >15% total body surface area at the Burn Unit of KBTH. Severe thermal burn was clinically defined as a thermal burn involving >20% TBSA. Selected patients were randomized into three groups A, B and C. The groups consisted of standard treatment [cetirizine arm (Group A)] and interventional arm [gabapentin (Group B) and combined cetirizine and gabapentin (Group C)]. Patients were randomly allocated to one of the three arms of treatment by simple ballot without replacement. The ballot box contained 21 sequentially labelled ballot papers of each treatment group (A, B and C), thus containing a total of 63 ballot papers.

The concealment was done by first wrapping the drugs in a foil before enveloping it in an opaque (brown) envelope and sealed by stapling. All the foil and envelope were of the same make. The patient's code and date were written on the back of the envelope. The sealed envelope was then given to the research assistant who was a qualified nurse in the Unit and was instructed on how to administer the drug to the patient. However, she was not told of the drug contained in the envelope. In the case of a missing or damaged drug, the pharmacist who carried out the assignment and could identify the number on the envelope replaced the envelope with the same drug.

Cetirizine, 10mg, was administered as a daily dose at 6am combined with 100mg vitamin C to group A participants (cetirizine alone group). The 100mg vitamin C was served again at 14 hours and 22 hours. (The dose of cetirizine remained a daily dose of 10mg throughout the length of the study as this was the standard treatment given at the unit where the study was conducted).

At maximum dose, gabapentin was administered as 300mg three times daily at 6hrs, 14hrs and 22hrs to the study participants recruited into the gabapentin group (group B). They will also receive 100mg vitamin C at the same hours. They, however, were started on the standard 300mg daily dose combined with vitamin C. This dose was increased to 300mg twice daily (600mg total dose) if there was no response to treatment as per VAS on day three, and then increased to the maximum dose of 300mg three times daily (900mg total dose). However, they were maintained on their current dose if there was improvement in symptoms until next review.

The Cetirizine-Gabapentin group will be administered a combined dosage of the two medications. Thus, they will be started on 10mg cetirizine combined with 300mg gabapentin as daily dose. The dose of gabapentin was increased to 300mg twice daily when the VAS score did not change whilst the cetirizine dose remained 10mg daily. On the third review day, when the effect of the drug had not increased significantly as per the VAS score, the dosage gabapentin was increased to 300mg three times daily while still maintaining the cetirizine dose of 10mg daily. They also received 100mg vitamin C 8 hourly in combination. This combined treatment was on the assumptions that since both drugs, cetirizine and gabapentin, have different mechanism of action (cetirizine acting peripherally and gabapentin acting centrally), their combined effect should be better than their individual effect.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cetirizine, gabapentin

Primary outcome(s)
Itch (pain) measured using the visual analogue scale at baseline, day 3, day 7, and day 14

Key secondary outcome(s))
1. Insomnia measured using the Athens Insomnia Scale at baseline, day 3, day 7, and day 14
2. Depression measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, day 3, day 7, and day 14

Completion date
10/03/2019

Eligibility

Key inclusion criteria
1. Patients aged 16–65 years age (assessments with VAS will be difficult in children and the elderly)
2. Patients with burns involving >15% TBSA (TBSA <15 patients are not admitted for treatment.
3. Patients hospitalised for more than 7 days
4. Patients who are proficient in English, Akan or Ga

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
69

Key exclusion criteria
1. Patients who undergo skin grafting involving 5% TBSA were excluded to maintain ‘pure’ cohort
2. Patients with co-morbidities including skin diseases, diabetes, chronic renal diseases, obstructive jaundice, pregnancy, etc. which by themselves caused itching
3. Patients who were septic
4. Patients with impaired cognitive ability
5. Patients with known hypersensitivity reactions

Date of first enrolment
12/06/2017

Date of final enrolment
18/12/2018

Locations

Countries of recruitment
Ghana

Study participating centre
National Reconstructive Plastic surgery and Burn Centre
Korle-Bu Teaching Hospital
Accra
Ghana
P.O Box KB 77

Sponsor information

Organisation
Ghana College of Physicians and Surgeons

ROR
https://ror.org/031jxes94

Funder(s)

Funder type

Other

Funder Name
Investigator Initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Data is available on request from Dr Elliott Arko-Boham by email barko_boham@chs.edu.gh

IPD sharing plan summary
Available on request