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Comparing the infection rates of ED patients with a sutured laceration (wound) on their scalp given hair washing instructions or told not to wash their hair

Submission date
14/11/2022

Recruitment status
No longer recruiting

Registration date
29/11/2022

Overall study status
Completed

Last Edited
03/10/2023

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Aftercare of sutured scalp wounds is always questioned by patients, including whether it is safe to wash their hair or not. Previous studies showed no increase in surgical site infection rate due to early washing of a sutured clean or clean-contaminated wound, compared to the conventional method of keeping the wound clean and dry with dressing. Several pilot studies on the effect of hairwashing on clean and clean-contaminated wounds consistently showed that early hairwashing does not increase the infection rate.
There is no study on contaminated or dirty wounds in the emergency setting and also no full trial on scalp areas for the effect on early hair washing and showering. This study compares hair-washing advice without wound care dressing on scalp laceration wounds compared with keeping clean and dry and wound care dressing by a healthcare professional. The potential benefit from early hair washing without wound care dressing on the scalp includes improved patient satisfaction, comfort, and saving medical consultation time and manpower, which may further reduce the cost of wound care. It is hoped that this new practice will not result in an increase in the infection rate of more than 3%.

Who can participate?
Patients over the age of 18 years with scalp lacerations

What does the study involve?
Participants are randomly allocated to the conventional group or the intervention group. The conventional group will be instructed to keep the wound clean and dry without hair washing or treatment and have a wound dressing every 1-3 days, and are not allowed to wash their hair until the stitches are removed.
The intervention group will be instructed to wash their hair after 48 hours from suturing, no more than two times a day and not less than every 2 days, with clean water by shower sprinkler or water tap, light massage of the non-sutured area, and with or without shampoo and conditioner but no antimicrobial ingredient, and then tap and blow until dry. No wound dressing

is needed for the intervention group. Participants are not advised to apply any other hair product on their hair/scalp except shampoo and conditioner, including but not limited to hair oil treatment and hair imaging products.
Participants will be reminded to go to the hospital immediately for any changes in wound condition, including ongoing bleeding or oozing, swelling, severe pain, erythema, warmth, or any other concern. Compliance will be monitored by a self-reported survey on the follow-up day and a telephone survey on Day 30.

What are the possible benefits and risks of participating?
Participants will not receive any direct benefits but they will help the researchers to gain a better insight into the management of sutured wound care which will eventually result in improved patient care. There will be no extra risk and discomfort for both groups on top of the existing risk of the suturing procedure including but not limited to infection, bleeding, scar formation, pain, and wound dehiscence (reopening).

Where is the study run from?
Queen Elizabeth Hospital (Hong Kong)

When is the study starting and how long is it expected to run for?
September 2021 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Man Tat Tam, Tmt468@ha.org.hk

Contact information

Type(s)
Principal Investigator

Contact name
Mr Man Tat Tam

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Early hair washing instruction on scalp laceration wound sutured in the emergency department: a randomized controlled noninferiority trial

Study objectives
The study hypothesis is that early hair-washing instruction on contaminated scalp laceration wounds sutured in the emergency department (ED) is not inferior in terms of surgical site infection to the instruction of no hair washing until the removal of stitches.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2021, Research Ethics Committee (KC/KE) (The Hospital Authority of Hong Kong, Hong Kong; +852 (0)3506 8139; ruby.chan@ha.org.hk), ref: KC/KE-21-0151/ER-3

Study design
Single-centre interventional non-blinded randomized controlled non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://drive.google.com/file/d/1u6hYA7Phhy62KBLrjuQrSPdjhlaK8Qwh/view?usp=share_link

Health condition(s) or problem(s) studied
Wound care in patients with scalp laceration wound sutured

Interventions
The subjects will be recruited by convenient sampling. A group of ED nurses will be invited as research assistants for this trial. After suturing procedure, the on-duty study nurse will screen

those patients with sutured scalp laceration wounds, assess the eligibility with the recruitment screening instrument, request consent, and perform randomization. Suitable candidates will be invited for their consent to the study. Followed by the recruitment and completion of consent to the study, the subject will be randomized by sequenced numbered, opaque sealed envelopes, which will be prepared by a third party not related to this study, with an allocation of ratio 1:1. To minimize bias of ED nurse who performs suturing, the subject recruitment and randomization will be conducted after the wound suturing procedure.

Subjects who are recruited for this study will be randomized to the conventional group and intervention group. The conventional group will be instructed to keep their hair clean and dry without hair washing or treatment, and have wound dressing in the general outpatient clinic (GOPC) every 1-3 days, and not be allowed to wash their hair until removal of stitches.

The intervention group will be instructed to wash their hair after 48 hours from suturing, no more than two times a day and not less than every 2 days, with clean water by shower sprinkler or water tap, light massage of the non-sutured area, and with or without shampoo and conditioner but no antimicrobial ingredient, and then tap and blow till dry. No wound dressing is needed for the intervention group. Subjects are not advised to apply any other hair product on their hair/scalp except shampoo and conditioner, including but not limited to hair oil treatment and hair imaging products.

A wound care leaflet will be given to both groups of subjects according to their randomization result. The conventional group will receive instruction to keep clean and dry and have wound care in a general outpatient clinic while the intervention group will be instructed to wash their hair after 48 hours without a dressing procedure.

Subjects will be reminded to attend an ED immediately for any change of wound condition, including ongoing bleeding or oozing, swelling, severe pain, erythema, warmth, or any other concern. Compliance will be monitored by a self-reported survey on the follow-up day and a telephone survey on Day 30.

Intervention Type
Behavioural

Primary outcome measure
Surgical site infection rate according to US CDC guidelines on the date of removal of stitches (Day 6-8) and Day 30

Secondary outcome measures
1. Pain level measured using a numeric score (0-10) on Day 1, Day 3, Day 5, overall until the date of removal of stitches and Day 30
2. Satisfaction rate measured using a numeric score (1-5) at the date of removal of stitches (Days 6-8) and Day 30

Overall study start date
01/09/2021

Completion date
10/06/2024

Eligibility

Key inclusion criteria
1. Patients over the age of 18 years
2. Activities of daily living (ADL)-independent
3. Scalp laceration not more than 5 cm, without tissue loss, requiring suturing
4. Mentally competent to give consent
5. Discharged from the ED and agree to return for the removal of sutures during the study period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
288

Key exclusion criteria
1. Patients who are under the age of 18 years
2. Not ADL-independent; mentally incompetent
3. Immunocompromised
4. Dirty wound (soiled by seawater or dirty water, with foreign body presented or infective)
5. Laceration longer than 5 cm
6. A wound that cannot be fully closed by stitches or with tissue loss
7. A wound that requires two-layer suturing or extended to the skull bone
8. Prescribed with antibiotics
9. Required hospitalization
10. Do not agree to return to the ED for follow-up and removal of sutures.

Date of first enrolment
01/10/2021

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
Hong Kong

Study participating centre
Queen Elizabeth Hospital
Accident and Emergency Department

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Sponsor information

Organisation
University of Hong Kong

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Sponsor type
University/education

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ROR
https://ror.org/02zhqgq86

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Man-Tat Tam (jerrytamqeh@gmail.com). Patient demographic (age/sex /academic level), wound type and size, infection rate, compliance rate, pain level score, and satisfaction level score data will be shared for 5 years after the overall trial end date. Consent was obtained at recruitment. All data are anonymous.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/11/2022	No	Yes