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Cost-effectiveness analysis of 2-octyl cyanoacrylate tissue adhesive and suture for closure of simple lacerations: Randomised Controlled Trial

Submission date
06/08/2007

Recruitment status
No longer recruiting

Registration date
24/08/2007

Overall study status
Completed

Last Edited
17/05/2019

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03040071

Study information

Scientific Title
Cost-effectiveness analysis of 2-octyl cyanoacrylate tissue adhesive and suture for closure of simple lacerations: Randomised Controlled Trial

Acronym
RCTWOUND

Study objectives
We hypothesised that although 2-octyl cyanoacrylate tissue adhesive is 15 to 20 times more expensive than suture in Hong Kong, that when all relevant costs were taken into consideration, that tissue adhesive would be the more cost-effective option.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained from the joint institutional research ethics committees of the Chinese University of Hong Kong and the Prince of Wales Hospital and from the research ethics committee of PYNEH on the 5th July 2005 (ref: CRE-2003.348 and CRE-2003.348-T).

Study design
A non-blinded, randomised controlled trial in the Emergency Departments (EDs) of two acute hospitals in Hong Kong.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Simple laceration wound repair

Interventions
Patients were randomly allocated to one of the two treatment groups using a computer generated randomised number system. One group received suturing materials (4-0 to 6-0 monofilament suture, Tyco Healthcare UK Ltd) and the other group received tissue adhesive (2-

octyl cyanoacrylate, Ethicon Inc.) for wound closure. A nurse on clinical duty opened a pre-coded envelope with details about treatment allocation and instructions on wound management.

All wounds were prepared in the same manner (cleansed with normal saline solution) before suturing or applying tissue adhesive. For the suture group, the wound was infiltrated with local anaesthetic (1% lignocaine solution) and the skin was closed using standard techniques with 4-0 to 6-0 monofilament suture. For the tissue adhesive group, local anaesthesia was not required for the procedure. 2-octyl cyanocrylate was painted over the apposed wound edges and 30 seconds were allowed for polymerisation to complete. Both treatment procedures were performed by nurses in EDs whom had been trained in the use of tissue adhesive by the principal investigator.

The duration for wound closure with suture and tissue adhesive are between 10 to 20 minutes. Participants will have follow-up at day 14, 30 and 90 after wound closure.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
2-octyl cyanoacrylate tissue adhesive

Primary outcome measure
The primary outcome measure was the Cosmetic Visual Analogue Scale (CVAS) score, measured at baseline, day 14, 30 and 90.

Secondary outcome measures
Secondary outcome measures included:
1. Visual Analogue Scale (VAS) score, measured at baseline, day 14, 30 and 90
2. Wound Evaluation Scale (WES) score, measured at day 14
3. Total time spent in each closure method
4. The overall patients' satisfaction, measured at day 30
5. The total costs required per patient in each method

Overall study start date
01/10/2005

Completion date
31/07/2006

Eligibility

Key inclusion criteria
All patients aged greater than or equal to 18 years presenting to the ED between 9 am to 5 pm, Monday to Friday, with traumatic lacerations or incised wounds were eligible for the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
60 patients for each group

Total final enrolment
186

Key exclusion criteria
To standardise the recruited cases for comparison, wounds with the following features were excluded:
1. Wound length greater than 8 cm
2. Deep wounds with muscle, tendon, bone, joint or neurovascular structure involvement
3. Scalp wounds
4. Vermilion border involvement at lip
5. Stellate lacerations
6. Stab wounds to the trunk or neck
7. Heavily contaminated or infected wounds
8. Animal or human bite
9. Wounds which required debridement of devitalised tissue
10. Wounds in which haemostasis could not be achieved within 20 minutes by direct pressure
11. Wounds greater than 12 hours old
12. We also excluded patients with a history of keloid formation or with physical or cognitive impairment making the use of visual analogue scales inaccurate

Date of first enrolment
01/10/2005

Date of final enrolment
31/07/2006

Locations

Countries of recruitment
Hong Kong

Study participating centre
Accident and Emergency Medicine Academic Unit
Shatin, NT
Hong Kong
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Sponsor information

Organisation
The Health and Health Services Research Fund (HHSRF) (Hong Kong)

Sponsor details
Research Fund Secretariat
Research Office
Food and Health Bureau
18/F, Murray Building
Garden Road
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Hong Kong
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rfs@fhb.gov.hk

Sponsor type
Government

Website
http://www.fhb.gov.hk/grants/english/funds/funds_hhsrf/funds_hhsrf_abt/funds_hhsrf_abt.html

Funder(s)

Funder type
Government

Funder Name
This study was supported by the Health and Health Services Research Fund (HHSRF) (Hong Kong) (project code 03040071).

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009	17/05/2019	Yes	No