Time-effectiveness of Mini-C-arm FLuoroscopy ASsisted Closed Reduction of Distal Radius Fractures versus Standard RadiograpH: The FLASH-trial, a randomized controlled trial

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The aim of the current study is to assess the potential time- and cost-savings of fluoroscopically aided reductions of dislocated DRFs in adult patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON48707

Source
ToetsingOnline

Brief title
FLASH

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
Fractured wrist, reposition of distal radius

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: OLVG Wetenschapfonds

Intervention

Keyword: Closed Reduction, Distal Radius Fractures, Mini-C-arm, Time-effectiveness

Outcome measures

Primary outcome

The primary outcome is the total time needed for reduction

Secondary outcome

Time in ED

Time of sub-processes of the reduction process

Acceptable reduction as defined by >15° radial inclination and >5 mm radial height and <20° volar tilt

Total amount of reduction attempts defined as removing the applied splint for a new reduction

Total amount of hematoma blocks administered

Initial management (conservative or surgical)

Radiation exposure per reduction attempt for the patient

Radiation exposure to the hands of the practitioner as measured by a ring dosimeter

Radiation exposure to the chest of the practitioner as measured by an electronic personal dosimeter which is attached to the lead apron at the height of the manubrium of the sternum

Secondary dislocation on a radiograph performed at one week warranting a change

from conservative to surgical management

Costs as defined by the difference in utilities by, amongst others, time,

splinting materials, amount of attempts and success-rate of reduction

Study description

Background summary

Initial management of dislocated distal radius fractures (DRFs) in the Emergency Department (ED) usually consists of closed reduction and splint application. When using a mini-C-arm device to fluoroscopically aid the reduction of DRFs in adult patients, this does not improve reduction quality when compared to standard reduction techniques. However, research regarding time- and cost-savings could elucidate potential benefits that could justify the use of a mini-C-arm device.

Study objective

The aim of the current study is to assess the potential time- and cost-savings of fluoroscopically aided reductions of dislocated DRFs in adult patients.

Study design

Randomized controlled trial

Intervention

Using a mini-C-arm to fluoroscopically aid the reduction process and perform post-reduction radiographs

Study burden and risks

A low level risk was estimated following a prospective risk analysis regarding the use of a mini-C-arm device in the ED performed by, amongst others, a radiological resident, a surgical resident, a healthcare technology expert and a medical physicist (Table 1).

Imaging procedures and estimated radiation exposure in both study arms:
The following calculations are based on reported radiation exposure in a study by Lee et al, radiation dose measurements during a demo session and data from the hospital PACS system.

Traditional reduction:
Two (AP + lateral) x-ray images pre-reduction without cast by Bucky: 0.2 mGy
Two (AP + lateral) x-ray images post-reduction with cast by Bucky: 0.4 mGy
Total radiation exposure: 0.6 mGy

Mini-C-arm reduction:
Two (AP + lateral x-ray images pre-reduction without cast by Bucky: 0.2 mGy
Three images (single shot, not continuous) without cast by mini-C-arm: 0.18 mGy
Two images (single shot, not continuous) with cast by mini-C-arm: 0.24 mGy
Total radiation exposure: 0.62 mGy

Estimated radiation exposure healthcare worker
As stated in the Besluit basisveiligheidsnormen stralingsbescherming the maximum allowed radiation exposure in the Netherlands for non-exposed healthcare workers) is 50 milisievert (mSv) or 50.000 microsievert (µSv) per year for the extremities and 1 mSv or 1000 microsievert per year for the body. Based on our own measurements using dosimeters, the estimated radiation exposure to the hands using the mini-C-arm is approximately 0.07-0.12 mSv or 7-12 microsievert (µSv) per image. During these tests, we did not measure any scatter radiation on any dosimeter that was not directly in the beam of the mini-C-arm, which is also confirmed by several studies. While performing a reduction, the practitioner will have to maintain the position of the reduced distal radius until a cast has been applied. This means that, while performing imaging during reduction, the hands of the practitioner will be near the direct beam of the mini-C-arm. To over-estimate the radiation exposure of the practitioner it is assumed that the hands of the practitioner are indeed positioned withing the primary x-ray beam, resulting in an exposure of not more than 0.18 mGy per procedure. With a total of 46 procedures, the total exposure is estimated at 8.3 mGy. Since it is highly likely that these procedures are performed by multiple individuals (approximately 20 practitioners that perform these reductions work in our ED), the estimated individual radiation exposure assuming a maximum of three reductions per person during this study is 0,54 mSv. Compared to the maximum allowed exposure of 50 mSv/year, this is a minor and acceptable radiation exposure that is well below the limits for healthcare professionals as set by the Dutch government. In addition no significant radiation exposure to the body is expected. However, practitioners will wear a lead apron during the procedure as obligated by hospital regulations

Estimated radiation exposure for the patient
For the patient no maximum allowed dose limits are set, but it is important to work according to the As Low As Reasonably Achievable (ALARA) principle. Risks were assessed following the guideline of the Netherlands Commission for Radiation Dosimetry, which suggests classification into three risk categories.
A medical physicist was involved in this risk assessment. Previous studies reported that radiation exposure in the mini-C-arm group is be lower than radiation exposure in the standard group, however, this has not been studied specifically in adult patients with a DRF requiring reduction. Based on the

above calculations the radiation exposure in both study arms are practically comparable, assuming one reduction attempt is needed. Any differences found are expected to be in a negligible range of several microsieverts. Therefore, the risk classification of this study following from the effective dose is category I, implicating a statistical probability of less than 5 in a million to develop radiation induced cancer. In this category, only a minor level of benefit is sufficient to approve research, including investigations that aim to increase knowledge, which is the purpose of this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients >=18 years
Presenting to the ED with a dislocated distal radius fracture requiring closed reduction

Exclusion criteria

Ipsilateral upper extremity fractures
Open fracture
Pregnancy
Neurovascular compromise requiring immediate surgical intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2019
Enrollment:	46
Type:	Actual

Medical products/devices used

Generic name:	Mini-C-arm
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-04-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL66132.100.18