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Randomized trial comparing effectiveness and safety of three percutaneous arterial closure devices vs manual compression in peripheral interventions

Submission date
30/07/2017

Recruitment status
No longer recruiting

Registration date
01/08/2017

Overall study status
Completed

Last Edited
14/09/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Peripheral arterial disease is a condition where fatty deposits build up in the arteries and restrict the blood supply to the leg muscles. Endovascular interventions (procedures that are done inside the blood vessels) have recently become the procedure of choice, in most cases, for the diagnosis and treatment of peripheral arterial disease. Over 5,000 endovascular procedures are performed annually in Spain for the diagnosis and treatment of PAD. An arterial access is required to perform these procedures. At first this was obtained by surgical dissection, but nowadays this step is avoided in most of cases thanks to the development of percutaneous techniques, where access is achieved through needle-puncture of the skin. Despite the advantages, these techniques pose other associated problems such as those related to the arterial puncture and stopping bleeding at the end of the procedure. After the procedure there are different arterial closure strategies that include direct manual compression over the puncture site, the use of mechanical devices to assist compression and, more recently, the use of percutaneous arterial closure devices. There are several mechanisms of action for these devices, and the most widely used are the collagen plug, percutaneous sutures and hemostatic clips. The use of these systems involves a risk of complications resulting from lack of effectiveness at stopping bleeding and inadequate delivery of the device. The available scientific evidence concerning these devices is scarce and of poor quality in many cases, with most results based on diagnostic procedures performed on the coronary (heart) arteries, which are not applicable to interventions performed on peripheral arteries. The aim of this study is to demonstrate that percutaneous arterial closure devices reduce the time needed to stop bleeding after percutaneous arterial access procedures performed on peripheral arteries, without decreasing the effectiveness and without increasing the risk of complications compared with manual compression.

Who can participate?
Patients aged over 18 undergoing percutaneous arterial access procedures for the diagnosis or treatment of peripheral arterial disease

What does the study involve?
Once the percutaneous arterial access procedure is finished, participants are randomly allocated to one of the following procedures to stop bleeding: collagen plug, metallic clip, suture mediated, or manual compression at the puncture site for at least 10 minutes and for additional periods of 5 minutes until bleeding stops. The effectiveness of the procedures is assessed by observing the absence of bleeding through the puncture site. The time needed to completely stop the bleeding is measured. The occurrence of complications related to the arterial puncture is assessed by physical examination and ultrasound performed 24 hours and 1 month after the intervention.

What are the possible benefits and risks of participating?
The results of this study can help to find out whether these devices are safe and effective in patients with peripheral arterial disease, who usually have more diseased arteries which are more complicated to puncture and have a higher risk of complications. If these devices can be safely used, many patients will have a better recovery with shorter hospital stays and will be able to walk sooner. The possible risks of these devices are acute arterial occlusion (blockage), infection, bleeding and/or hematoma (a solid swelling of clotted blood).

Where is the study run from?
Hospital Virgen de la Salud de Toledo (Spain)

When is the study starting and how long is it expected to run for?
January 2012 to June 2014

Who is funding the study?
Hospital Virgen de la Salud de Toledo (Spain)

Who is the main contact?
Dr Javier Peinado Cebrina

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number

PACD1

Study information

Scientific Title
Effectiveness and safety of three percutaneous arterial closure devices (collagen plug, metallic clip and suture mediated) compared to manual compression in hemostasis after percutaneous transfemoral arterial procedures in peripheral territories

Study objectives
Percutaneous arterial closure devices achieve hemostasis in the arterial femoral access faster than standard manual compression, without increasing the risk of complications related to arterial access site and improving the comfort of the patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of clinical research (Comité ético de investigación clínica) of the Complejo Hospitalario de Toledo, 18/01/2012, ref: 82

Study design
Interventional prospective randomized controlled non-masked single-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral arterial disease

Interventions
Patients are assigned randomly, by means of a computer generated number, at the end of the procedure to receive hemostasis of the femoral arterial access site with one of the three arterial closure devices tested (collagen plug [Angioseal], metallic clip [Starclose] or suture mediated [Perclose ProGlide]) or manual compression at the puncture site for at least 10 minutes and for additional periods of 5 minutes until complete hemostasis is achieved.

Effectiveness of the hemostatic procedures will be assessed by observation of the absence of bleeding through the puncture site. Time necessary to achieve complete hemostasis will be measured. Occurrence of any complication related to the arterial puncture will be assessed by physical examination and ultrasonography performed 24 hours and 1 month after the intervention.

Intervention Type
Mixed

Primary outcome(s)

Effectiveness of the hemostatic procedure applied, assessed by observation of the absence of bleeding through the puncture site immediately after the application of the hemostatic system, 24 hours later and 1 month later

Key secondary outcome(s))
Occurrence of complications related to arterial access site, assessed by postprocedure physical examination, echo doppler at the arterial access, and blood test at 24 hours and 1 month post intervention

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Patients intervened percutaneously for treatment or diagnostic of peripheral arterial disease through femoral access in the Department of Angiology and Vascular Surgery of the Hospital Virgen de la Salud de Toledo
2. Aged over 18

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Known contraindications for any of the percutaneous arterial closure devices tested
2. Deny of the patient to sign the informed consent document

Date of first enrolment
01/06/2012

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Virgen de la Salud
Toledo
Spain
45003

Sponsor information

Organisation
Hospital Virgen de la Salud de Toledo

ROR
https://ror.org/0289cxp23

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Virgen de la Salud de Toledo

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Javier Peinado Cebrina.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2018	14/09/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes