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Use of patient blood to treat air collecting around the lung

Submission date
22/03/2016

Recruitment status
No longer recruiting

Registration date
24/03/2016

Overall study status
Completed

Last Edited
24/03/2016

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
A pneumothorax is a serious condition in which air leaks into the space between the lung and the chest wall. This air pushes against the outside of the lung, causing it to collapse. Lung tissue that is damaged because of an underlying disease is more likely to develop pneumothorax as a complication (secondary spontaneous pneumothorax, SSP). When someone is suffering from SSP, it is very important to equalise the pressure in the chest so that the lungs can inflate properly. This is done by placing tubes into the space around the lungs in the chest (pleural cavity) so that any air can drain out of the chest (chest drainage). In some people, the air leak does not seal after chest drainage, and further treatment such as surgery is needed (persistent air leak). Persistent air leaks can be dangerous, as chest drains need to be left in place longer, which increases the risk of infection. Autologous blood patch pleurodesis is a technique in which the patient's own blood is injected into the chest drain in order to "patch up" the air leak. The aim of this study is to investigate the effectiveness of early autologous blood-patch pleurodesis in the treatment of SSP.

Who can participate?
Adults with SSP who are unable or unwilling to have surgery.

What does the study involve?
After the chest drains are put in place, participants are randomly allocated to one of two groups. Those in the first group have 50ml of their own blood injected into the chest drain on day three. If the air leak continues, this procedure is repeated on day five and day seven. Participants in the second group do not receive any injections of their blood, and are observed in the usual manner for 10 days. After this, participants in this group can receive the autologous blood patch pleurodesis on day 10, 12 and 14. Over the 10 days of the study (before the second group are given the chance to have the procedure), participants in both groups are examined every day in order to find out if the air leak is sealed. Once the air lead has stopped, participants are kept under observation in hospital for one or two days before being discharged. The length of time until the air leak stops and until patients are discharged from hospital is recorded in both groups. Participants also attend a follow up appointment a week after they are discharged to make sure that the air leak is still sealed.

What are the possible benefits and risks of participating?
Participants may benefit from a quicker discharge from hospital. There are no notable risks of taking part in the study.

Where is the study run from?
Menoufia University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
September 2012 to February 2016

Who is funding the study?
Menoufia University Faculty of Medicine (Egypt)

Who is the main contact?
Dr Islam Ibrahim

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Early Autologous Blood-patch Pleurodesis versus Conservative Management for Treatment of Secondary spontaneous pneumothorax: a randomised controlled trial

Study objectives
The aim of this study is to investigate whether early autologous blood-patch pleurodesis is better than conservative treatment for the management of secondary spontaneous pneumothorax.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee - Menoufia University Faculty of Medicine, 03/10/2012

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Secondary spontaneous pneumothorax

Interventions
Following chest drain insertion, participants are randomly allocated to one of two groups.

Group 1: Participants have intra-pleural instillation of 50ml autologous blood into the chest drain on day 3 of chest drain insertion. If the air leak continues, the procedure is repeated on day 5 and day 7. Once the air leak has stopped the drain is removed after 1-2 days and the patient observed for 2-3 days before discharge from the hospital. Participants attend a follow up visit after 1 week in which they have a chest X-ray.

Group 2: Participants are observed for air leak for 10 days. If the air leak persists after 10 days, then participants receive the intra-pleural instillation of 50ml autologous blood into the chest drain, which can be repeated on day 12 and 14. Once the air leak has stopped the drain is removed after 1-2 days and the patient observed for 2-3 days before discharge from the hospital. Participants attend a follow up visit after 1 week in which they have a chest X-ray.

Intervention Type
Procedure/Surgery

Primary outcome measure
Time between insertion of chest drain and air leak stoppage is measured through daily clinical observations.

Secondary outcome measures
Length of hospital stay is measured in days.

Overall study start date
01/09/2012

Completion date
15/02/2016

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Secondary spontaneous pneumothorax
3. Unfit or unwilling to have surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 - 50

Key exclusion criteria
Not meeting the inclusion criteria.

Date of first enrolment
01/11/2012

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
Egypt

Study participating centre
Menoufia University Hospital
Gamal Abdel Nasser Street
Shibin Al Kawm
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32513

Sponsor information

Organisation
Menoufia University Faculty of Medicine

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Sponsor type
University/education

ROR
https://ror.org/05sjrb944

Funder(s)

Funder type
University/education

Funder Name
Menoufia University Faculty of Medicine

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/04/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request