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Manual aspiration versus digital drainage system in spontaneous primary pneumothorax

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2016	Respiratory	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pneumothorax (collapsed lung) occurs when air leaks into the space between the lungs and chest wall. This buildup of air puts pressure on the lung, so it cannot expand as much as it normally does when you take a breath. In most cases only part of the lung collapses, in which case the patient is monitored with a series of chest X-rays until the air is completely absorbed and the lung has re-expanded. This may require bed rest as any exertion may aggravate the collapse. Supplemental oxygen can speed up the absorption process. If a larger area of the lung has collapsed, it's likely that a needle or chest tube will be used to remove the air. The hollow needle or tube is inserted between the ribs into the air-filled space that is pressing on the collapsed lung. A syringe is attached so the doctor can pull out the excess air - just like a syringe is used to pull blood from a vein. This is called manual aspiration. Chest tubes can also be attached to a suction device (digital drainage device) that continuously removes air from the chest cavity and may be left in place for several hours to several days. The aim of this study is to compare the effectiveness of manual aspiration with a syringe versus a digital drainage device.

Who can participate?
Patients with a pneumothorax

What does the study involve?
Participants are randomly allocated to be treated with either manual aspiration or a digital drainage device. Six hours later participants undergo a chest x-ray to assess the effectiveness of the treatment.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Donostia Hospital (Spain)

When is the study starting and how long is it expected to run for?
September 2011 to September 2014

Who is funding the study?
Hospital Donostia (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NEI0111

Study information

Scientific Title
Manual Aspiration Versus DIgital drainage system in spontaneous primary pneumothorax: open blinded two parallel group randomised controlled trial

Acronym
AMVADI

Study objectives
AMVADI Aspiración manual versus aspiración digital (Manual aspirtion versus digital aspiration)

Spontaneous pneumothorax is an extremely frequent pathology. Despite this, there is no clear consensus on managing these patients. Therefore, there are three systematic reviews that compare percutaneous aspiration with tube drainage for treating idiopathic spontaneous pneumothorax. The conclusion of these systematic reviews is that percutaneous aspiration is

similar or even better than tube drainage in terms of resolution of the pneumothorax, rates of relaps and hospital admission. We think that aspiration with digital drainage device is even better than manual aspiration for treating primary spontaneous pneumothorax in terms of resolution of the pneumothorax, rates of relaps and hospital admission.

Digital drainage sytem is more effective than manual aspiration in terms of resolution of the pneumothorax, rates of relapse and hospital admission for treating idiopathic spontaneous pneumothorax.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee [Comité Ético de Investigación Cínica], Gipuzkoa, 20/10/2010, ref: 9/2010

Study design
Single-centre open blinded two parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Spontaneous primary pneumothorax

Interventions
Control arm:
A plastic catheter (Pleurocaht 8Fr) is inserted into the second anterior intercostal space on the midclavicular line. The air is pulled out with manual syringe (50cc, until 3500cc or until the excess of air ends).Thereafter, the catheter is closed and a chest X ray performed six hours later (accepted range 4-12h to ensure the patient's sleep). If lung expansion is complete, or if only a small rim of apical pneumothorax is present, the patient is discharged. If no lung expansion or only partial expansion is or a continuous air leak is observed the patient is connected to a water seal aspiration device and proceed to hospital admission.

Intervention arm:
A plastic catheter (Pleurocaht 8Fr) is inserted into the second anterior intercostal space on the midclavicular line. The catheter is connected to a digital aspiration device (Thopaz), regulated to

generate a negative pressure of 10 cmH2O. Aspiration is performed until cessation of air occurred or for a maximum of 30 mins. Thereafter, the catheter is closed and a chest X ray performed six hours later (accepted range 4 - 12hours to ensure the patient's sleep). If lung expansion is complete, or if only a small rim of apical pneumothorax is present, the patient is discharged. If no lung expansion or only partial expansion is or a continuous air leak is observed the patient is connected to a water seal aspiration device and proceed to hospital admission.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pneumothorax resolution in chest X ray performed six hours after the catheter insertion, accepted range 4-12h to ensure the patient's sleep

Secondary outcome measures
1. Risk of hospital admission
2. Relapse of pneumothorax
3. Resolution after 1 week
4. Percentage of patients that need surgery
5. Percentage of smoking cessation

Overall study start date
01/09/2011

Completion date
01/09/2014

Eligibility

Key inclusion criteria
Patients with first episode of primary spontaneous pneumothorax

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
104 patients (52 in each of the arms)

Key exclusion criteria
1. Traumatic or iatrogenic pneumothorax
2. Secondary pneumothorax
3. Catamenial pneumothorax
4. Previous epidodes of oneumothorax
5. Bialteral pneumothorax

6. Tension pneumothorax
7. Immunosuppresion

Date of first enrolment
01/09/2011

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Spain

Study participating centre
Paseo Mons 76, 1A
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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ROR
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Donostia (Spain)

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