AIR-NET

Pharmacy IMP Dispensing & Accountability

Treatment Overview

Participants will be randomly assigned to receive a 28-day treatment period of either:

- Usual care
- Disulfiram (two x 200 mg oral tablets once daily)
- Dipyridamole (one x 200 mg oral prolonged/modified release capsule twice daily)
- Doxycycline (one x 100 mg oral capsule once daily)

This trial is open label. The trial team, pharmacy team & the trial participants will be aware of the treatment allocation.

Supply of IMP

- IMP will not be provided, this should be procured through local pharmacy stocks
- Any brand is permitted
- Pharmacy manual states a minimum stock required before recruitment begins & that should be maintained throughout the trial duration.
- Where a site has difficulty obtaining the supply of medication for any of the treatment arms, the site will continue to recruit and randomise participants between the available treatment arms and usual care at that site.

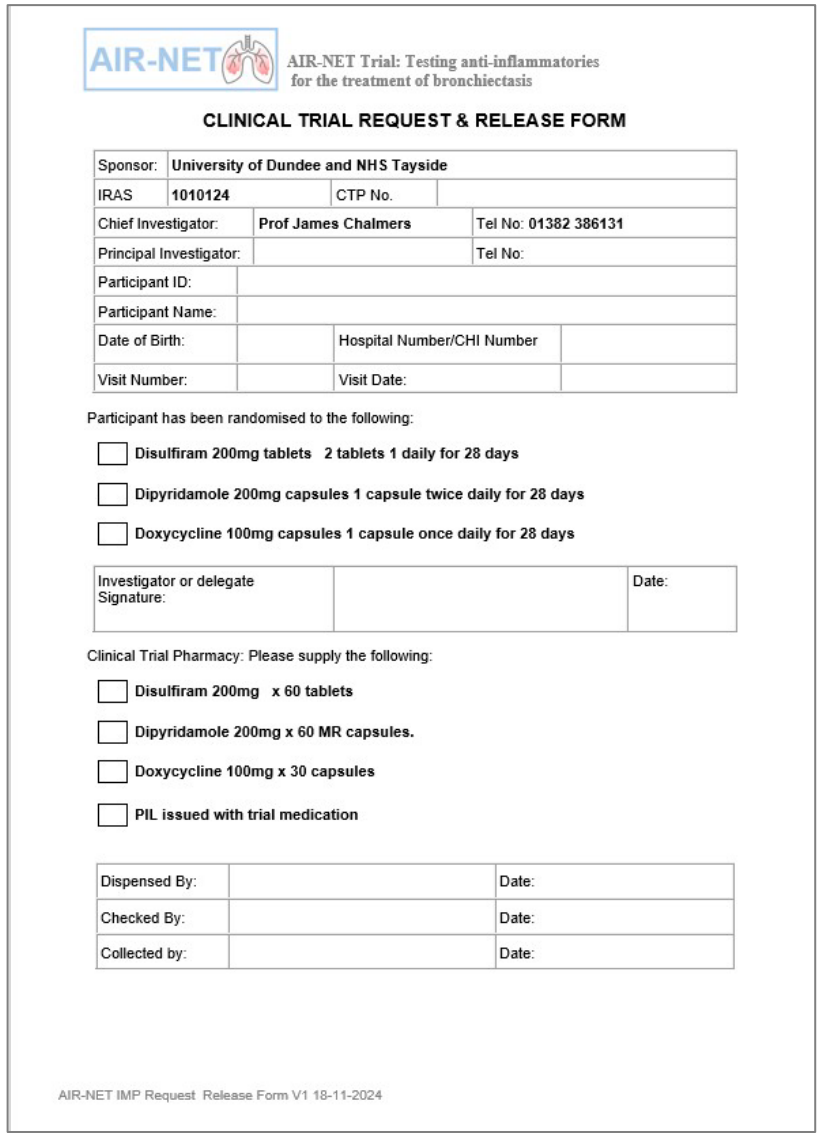
IMP	Minimum stock required
Disulfiram 200 mg tablets	2 x 50
Dipyridamole 200 mg capsules	2 x 60
Doxycycline 100 mg capsules	2 x 50

IMP Request/ Release Form

- Pharmacy will receive an IMP Request & Release Form from the research team after randomisation has taken place (appendix 1)
- Research team will document participant details & randomisation allocation
- This must be signed & dated by PI or delegated doctor
- Randomisation email to be printed & take with IMP Request/Release Form

Pharmacy to complete:

- Tick box to confirm the manufacturer PIL has been issued with the trial medication
- Record who dispensed & checked IMP
- Record research team member who collects IMP
- Completed forms to be filed in PSF, copy to be filed in patient's medical notes



AIR-NET AIR-NET Trial: Testing anti-inflammatories for the treatment of bronchiectasis

CLINICAL TRIAL REQUEST & RELEASE FORM

Sponsor:	University of Dundee and NHS Tayside		
IRAS	1010124	CTP No.	
Chief Investigator:	Prof James Chalmers	Tel No: 01382 386131	
Principal Investigator:		Tel No:	
Participant ID:			
Participant Name:			
Date of Birth:		Hospital Number/CHI Number	
Visit Number:		Visit Date:	

Participant has been randomised to the following:

- ☐ Disulfiram 200mg tablets 2 tablets 1 daily for 28 days
- ☐ Dipyridamole 200mg capsules 1 capsule twice daily for 28 days
- ☐ Doxycycline 100mg capsules 1 capsule once daily for 28 days

Investigator or delegate Signature:		Date:

Clinical Trial Pharmacy: Please supply the following:

- ☐ Disulfiram 200mg x 60 tablets
- ☐ Dipyridamole 200mg x 60 MR capsules.
- ☐ Doxycycline 100mg x 30 capsules
- ☐ PIL issued with trial medication

Dispensed By:		Date:
Checked By:		Date:
Collected by:		Date:

AIR-NET IMP Request Release Form V1 18-11-2024

Dispensing IMP

- IMP dispensed should provide required number of tablets/capsules for the trial treatment duration
- The IMP can be removed from the original packaging and repackaged for clinical trial dispensing
- The manufacturer PIL must be issued with trial medication. This can be provided from the original medication pack, photocopied or printed from the electronic medicines compendium
- Total tablets/capsules to be dispensed:

IMP	Dose	Duration	Total required
Disulfiram 200 mg tablets	2 tablets, once daily	28 days	60
Dipyridamole 200 mg capsules	1 capsule, twice daily	28 days	60
Doxycycline 100 mg capsules	1 capsule, once daily	28 days	30

IMP Labelling

- The IMP outer packaging must be labelled with a clinical trial label
- Labelling requirements are detailed in the pharmacy manual
- An example label is provided, clinical trial pharmacy can produce their own label with these requirements

Example template label for Disulfiram	AIR-NET Trial Contains: Disulfiram 200 mg, 60 tablets Directions for use: Take 2 tablets, once daily for a total of 28 days. For oral use only. Store below 25°C.	
	Participant ID	
	Participant name	
	Date of dispensing	
	Expiry date	
	Batch number	
	Chief Investigator: Prof James Chalmers, Ninewells Hospital, Dundee DD1 9SY. Tel: 01382 383642 IRAS number: 1010124 Keep out of the sight and reach of children For clinical trial use only	

IMP Accountability

An accountability log is provided in the PSF, this can be completed on paper or electronically

This must record IMP accountability for each trial medication:

- Hospital supply:
  - date received
  - quantity,
  - batch number
  - expiry
- IMP issuing: participant ID, date issued, quantity, signed by pharmacist performing release
- IMP returns: date, quantity, signature
- IMP disposal: date & signature

IMP Accountability Log

AIR-NET Trial: Testing anti-inflammatories for the treatment of bronchiectasis

A randomised, open-label, multifactorial, multicentre, platform trial using a range of repurposed anti-inflammatory treatments to improve outcomes in patients with bronchiectasis within the EMBARC clinical research network.

IMP ACCOUNTABILITY FORM FOR PHARMACY

IRAS	1010124	**Chief Investigator**	Prof James Chalmers		
Local CTP ID		**Principal Investigator**		**Tel No**	

IMP	

FROM HOSPITAL SUPPLY				**ISSUED**				**RETURNED**			**DISPOSED OF**	
Date received	Quantity	Batch Number	Expiry	Participant ID	Date	Quantity (capsules/ tablets)	Signature	Date	Quantity (capsules/ tablets)	Signature	Date	Signature

Please complete a separate accountability log for each IMP for AIR-NET.

Comments:

Signed for Pharmacy: Date:

AIR-NET

Trial Visits

All visits

• Participant Transport

Participants should be offered a taxi to bring them to the appointment and return them home. This has been proven to help recruitment and retention of trial participants.

An account should be set up with a local taxi company for this as per local practice.

Alternatively, participants wishing to use public transport should have their cost reimbursed or petrol paid. This should be done as per local procedure e.g. from petty cash or by completing a travel expense form.

• Participant Identity

Participant identity should be checked at each visit. Some examples of identification are listed below:

- Passport
- Driving licence
- Current matriculation card
- Young person's or senior citizen's railcard
- Proof of Address
- National Insurance Card
- CHI Number/Medical Card

All visits

Participant trial ID

- All participants consented to the trial should be allocated a participant ID number.
- Participant ID numbers are made up of five numbers:
- First two numbers to indicate the site and
- Last three indicate the participant number at that site.
- E.g. 01001 is the first participant at site one.
- Use participant ID numbers in order
- Ensure site ID is correct for your site.
- If participant fails screening, and does not go on to randomisation, their participant ID number should not be re-used.

Worksheets

- Worksheets are available to facilitate data collection
- Their use is not mandatory
- If worksheets are used to record source data, they must be filed in the medical notes.

Visit 1 Screening (-35 days to day 0)

- Informed Consent
- Eligibility check
- Demographics
- Medical history
- Con meds
- Physical Exam
- Height & weight
- Vital signs
- ECG
- Full blood count & research bloods.
- Sputum sample for eligibility & research
- Post bronchodilation spirometry
- Pregnancy test if applicable
- Questionnaires

Visit 1: BEST diary

Completion of BEST Diary

Participants have 3 options (discuss their preference and record this at visit 1 on the eCRF):

Complete the diary on the paper form
Complete the diary through Castor Connect App
Complete the diary online using a web browser
(participants will receive a daily email reminder via a weblink)

The diary is completed every day from day 0 (visit 2) to day 28 (visit 5)

Important points:
If the participant chooses to complete the diary online (either app or browser, you must collect their email address and add this to Castor **during visit 1**

You must enter visit 2 data (at a minimum the visit date) **on the day of the visit**
This is to allow the email notifications to be set up for the following day (day 1)

Visit 2 Baseline & Randomisation

- Continued Consent
- Eligibility check
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- 6-minute walk test
- Research blood sample
- Research sputum sample
- Nasal sample
- Pregnancy test if applicable
- Questionnaires
- Randomisation
- Dispensing trial drugs

Visit 3 (day 7)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- Post bronchodilation spirometry
- Research blood sample
- Research sputum sample
- Pregnancy test if applicable
- Questionnaires

Visit 4 (day 14)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- Post bronchodilation spirometry
- Full blood count, urea and electrolytes, liver function test
- Research blood sample
- Research sputum sample
- Pregnancy test if applicable
- Questionnaires

Visit 5 (day 28)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- 6-minute walk test
- Post bronchodilation spirometry
- Full blood count, urea and electrolytes, liver function test
- Research blood sample
- Research sputum sample
- Nasal sample
- Pregnancy test if applicable
- Questionnaires
- Drug accountability

Visit 6 (day 56)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- Post bronchodilation spirometry
- Full blood count, urea and electrolytes, liver function test
- Research blood sample
- Research sputum sample
- Questionnaires

Safety Visits (as required)

Participants will be requested to attend an unscheduled safety visit if they experience a bronchiectasis exacerbation or any other safety concern

- Concomitant medications check
- Review/recording of adverse events
- Review/recording of exacerbations
- Vital signs
- Post bronchodilation spirometry
- Safety bloods
- Research bloods, as per lab manual
- Research sputum sample collection

Visit windows

Missed trial assessments or trial medication, or visits completed outside the visit window, will not be reported as breaches, where this is due to participant choice or a clinical decision.

Visits 2,3,4 and 5 should be every 7 days. If a participant is unable to attend on the scheduled visit day, then a delay of up to 2 days is acceptable, after which it becomes a missed visit.