

A randomised controlled trial to assess the role of resistance assays in Human Immunodeficiency Virus (HIV) infection

Submission date
23/01/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
23/01/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
19/04/2007

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RDC01658

Study information

Scientific Title

Acronym

ERA - Evaluation of Resistance Assays

Study objectives

The main hypothesis is that providing genotypic resistance assays improves the treatment of HIV-infected individuals who are not highly treatment-experienced. A subsidiary hypothesis is that phenotypic plus genotypic resistance testing is superior to genotypic resistance testing alone in HIV-infected individuals who are highly treatment-experienced.

The ERA trial was designed to assess the clinical utility of HIV resistance testing in patients who had failed therapy and whose most recent viral load was at least 2000 copies/ml. Patients were randomised to one of two parts, depending on whether the clinician was able (Part A) or was not able (Part B) to select a regimen of 3 or more drugs that, with reasonable expectation, had potent anti-HIV activity and to which each drug contributed. Patients in Part A were allocated to (a) no resistance test, or (b) a centralised genotypic assay (VIRCOGENTM). All participants in Part B had the VIRCOGENTM assay and were randomised to have or not have in addition a centralised phenotypic assay (ANTIVIROGRAMTM). Patients allocated to resistance testing had access to testing at any time during follow-up when clinically indicated, according to the original allocation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Infection and infestations: HIV/Acquired Immunodeficiency Syndrome (AIDS)

Interventions

1. Standard care
2. Access to a centralised genotypic assay with computer assisted interpretation
3. Access to a centralised phenotypic assay

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Plasma HIV-1 RNA at 12 months measured centrally at the Royal Free Hospital using the Roche ultra-sensitive assay (with a lower limit of detection of 50 copies/ml).

Secondary outcome measures

1. CD4 count at 12 months (all laboratories participate in the UK National Quality Assessment Scheme of SD4)
2. Antiretroviral treatment prescribed including the number of switches in therapy and drugs used (constructed from 3-monthly case record forms)
3. Adherence with antiretroviral treatment prescribed (assessed by a 3-monthly self-completed questionnaire)
4. Available drug options (as assessed by genotypic resistance) at 12 months
5. Progression to a new AIDS-defining events will be collected retrospectively on an annual basis after 12 months to enable long-term benefits to be assessed

Overall study start date

01/02/2000

Completion date

01/08/2002

Eligibility

Key inclusion criteria

1. Confirmed HIV-positive
2. Age 18 years or more
3. Expected to live at least 12 months
4. Able to give informed consent
5. Currently receiving antiretroviral therapy
6. Most recent HIV ribonucleic acid (RNA) >2000 copies/ml
7. Clinician and patients have decided to change therapy on the basis of virological failure
8. Clinician considers that a resistance test may influence selection of new drug regimen, and clinician and patient are prepared to wait for the result (up to 1 month) before changing treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

480

Key exclusion criteria

1. Naive to antiretroviral drugs or previous exposure to 1 or 2 nucleoside analogue reverse transcriptase inhibitors only
2. Part A only: a resistance test (genotypic or phenotypic) had previously been performed or patient would have had a local resistance test
3. Part B only: a phenotypic resistance test had previously been performed
4. Participation in certain trials of antiretroviral therapies, considered on a case-by-case basis
5. Was unlikely to comply with routine schedule of visits

Date of first enrolment

01/02/2000

Date of final enrolment

01/08/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
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Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive London

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	15/04/2005		Yes	No