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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 19/04/2007	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr David Dunn

Contact details
MRC Clinical Trials
222 Euston Road
London
United Kingdom
NW1 2DA
+44 (0)20 7670 4739
d.dunn@ctu.mrc.ac.uk

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
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

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