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A randomised controlled trial of mobile phones to influence adherence to first line antiretroviral treatment among human immunodeficiency virus (HIV) infected patients in South India

Submission date	Recruitment status	[X] Prospectively registered
18/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/07/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/10/2016	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hivind.eu/

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
The antiretroviral roll out for human immunodeficiency virus (HIV) in India (HIVIND) - strengthening capacity to promote adherence and patient follow-up in the context: a two-centre, randomised, controlled, open trial in South India to study an innovative approach using mobile phones delivery to promote adherence in antiretroviral naive, HIV+ Indian patients

Acronym
HIVIND

Study objectives
Antiretroviral treatment (ART) naive patients started on ART, followed up for 24 months after ART initiation, and receiving reminders on their mobile telephones will have better adherence and hence, a longer time to resistance development than patients who do not receive such reminders over the same period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Sweden: Karolinska Institutet, Stockholm, 18/03/2009, ref: 2009/303 - 31/2
2. Finland: University of Tampere, 21/04/2009, ref: R09064
3. India: St. John's National Academy of Health, Bangalore, 20/03/2009, ref: IERB/1/172/09
4. India: YRG Care, Chennai, 18/04/2009
5. Vietnam: Hanoi Medical University, 02/02/2009, ref: 66/HMURB

Study design
Two-centre randomised controlled open trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Can be found at http://ki.se/content/1/c6/03/05/79/HIVIND%20participant%20info%20ISRTCN.pdf

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
Both arms will receive mobile telephones. However in the control arm, there will be no further interaction via the mobile phone. In the intervention arm, the mobile phone intervention will be as described below:
1. Each of the 300 patients in the intervention arm will receive a cell phone (handset) with free incoming calls, and a set amount of talk time per month which will be prepaid by the project (approximately Rs 200 per phone per month). The talk time is included to allow functionality of the phone, and expiry of the talk time will not disallow any of the project related communications (this has been discussed with the mobile network company).
2.1. Automated voice calls (IVR) reminding patients to take their medication will go out once a week at a specified time to each of the 150 patients in the intervention arm at each site. This will be in Kannada, Telugu or Tamil, depending on the language the patient speaks. If the patient for any reason does not receive this call, then a repeat call is sent within the next hour.
2.2. A second weekly 'adherence reminder contact' will be made by hospital counsellors, from a number based at the hospital and dedicated to this purpose, to remind the patients about his medication (a standard script for this part of the conversation), enquire about the patients' wellbeing, follow up on any pending issues. (These calls will be scheduled on the 4th day after the IVR has been sent out).
3. Patients will report back once a day to record that they have taken their medication. A simple functionality for this has been developed involving two clicks of the phone.

In the event of non-receipt of such a message or a negative response, an automatic reminder will be sent to the patient 24 hours later.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time to occurrence of virological failure (defined as having greater than 400 copies/ml on two consecutive measures at least one month apart. Date of failure is documented as the date of initial reading of the value greater than 400 copies/ml.

Secondary outcome measures
Self-reported adherence expressed as a percentage

Overall study start date
01/09/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria

1. Human immunodeficiency virus (HIV) seropositive
2. Aged between 18 - 60 years, either sex
3. Meet criteria to start ART (in India, ART is indicated for symptomatic patients with a World Health Organization [WHO] Clinical Stage 4 condition regardless of CD4 counts and plasma viral load; WHO Stage 3 condition with CD4 less than 350/mm^3 and in asymptomatic patients, with CD4 count less than 200/mm^3)
4. ART naive (i.e. no prior antiretroviral therapy or ART for less than 7 days)
5. Residence in the Southern Indian States with the ability to visit clinic regularly for follow-up visits

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Severely ill (Karnofsky score less than 70) at the time of recruitment
2. Impaired renal function (creatinine greater than 2 times upper limit of normal)
3. Study participant already recruited in the same household
4. Non-availability of mobile telephone network

Date of first enrolment
01/09/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
India

Sweden

Study participating centre
Karolinska Institutet
Stockholm
Sweden
SE 171 77

Sponsor information

Organisation
European Union (EU) (Belgium)

Sponsor details
Directorate - General for Research
Directorate F - Health
CDMA 02/66
Brussels
Belgium
B 1049

Sponsor type
Government

Website
http://cordis.europa.eu/fp7/

ROR
https://ror.org/019w4f821

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	10/03/2014		Yes	No
Results article	results	24/10/2014		Yes	No
Results article	results	02/11/2015		Yes	No
Results article	results	27/01/2016		Yes	No