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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 |