

Baseline health survey of the communities around the concession area of the proposed Simandou project in Guinea

Submission date 15/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/05/2010	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

N/A

Study information

Scientific Title

Baseline health survey of the communities around the concession area of the proposed Simandou project in Guinea: A cross-sectional household-based and school-based epidemiological survey

Acronym

BHS Simandou Guinea

Study objectives

A baseline health survey will provide quality data for profiling the health status of communities potentially affected by a large-scale iron ore project in a remote area of Guinea. Such data will become the benchmark to monitor future project-related health impacts.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the National Ethics Committee for Health Research (Comite National d'Ethique pour la Recherche en Sante [CNERs]) (ref. 04/CNERs/10)

Study design

Cross-sectional household-based and school-based epidemiological survey in 14 sentinel sites

Primary study design

Observational

Secondary study design

Cross-section survey

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

1. Community sensitization documents (in poster format at central locations in sentinel sites (e. g. health post) 2. Written informed consent sheet

Health condition(s) or problem(s) studied

Baseline health survey (malaria, intestinal parasites, anaemia, malnutrition, hypertension)

Interventions

1. Antimalarial treatment (artemunate-amodiaquine)
2. Anthelmintic treatment (albendazole plus praziquantel)
3. Iron and vitamin supplement

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Anaemia prevalence (according to standard WHO criteria)
2. Malaria prevalence (according to rapid diagnostic tests)
3. Prevalence of stunting and wasting
4. Prevalence of hypertension
5. Prevalence and intensity of intestinal parasites (helminths)

Secondary outcome measures

Health-related knowledge, attitudes and practices in adult population

Overall study start date

19/05/2010

Completion date

03/06/2010

Eligibility**Key inclusion criteria**

1. Written informed consent by head of household
2. Written informed consent by parents and/or legal guardians for children aged <15 years
3. The following inclusion criteria will be applied according to specific surveys:
 - 3.1. Questionnaire survey: adult population (aged >15 years)
 - 3.2. Anaemia survey: children aged < 5 years and women in reproductive age (15-49 years)
 - 3.3. Malaria prevalence survey: children aged < 5 years
 - 3.4. Anthropometric survey: children aged < 5 years
 - 3.5. Blood pressure survey: adult population (aged >15 years)
 - 3.6. Parasite prevalence survey: school-aged children (aged 6-15 years)

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

Approximately 2,240 individuals (i.e., 280-420 households (median: 35); estimated mean household size: 5 individuals (n=1,750); plus 14 schools with 35 children per school (n=490)

Key exclusion criteria

No written informed consent

Date of first enrolment

19/05/2010

Date of final enrolment

03/06/2010

Locations

Countries of recruitment

Guinea

South Africa

Study participating centre

NewFields LLC

Irene

South Africa

Pretoria

Sponsor information

Organisation

Rio Tinto SIMFER SA (Guinea)

Sponsor details

Immeuble Kankan - Cité chemin de fer

Conakry

Guinea

BP 848

Sponsor type

Industry

Website

<http://www.riotintosimandou.com/>

ROR

<https://ror.org/05m7zw681>

Funder(s)

Funder type

Industry

Funder Name

Rio Tinto, Simandou Iron Ore Project (Guinea)

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