

Piloting the global subsidy: the impact of subsidised artemisinin-based combination therapies distributed through private drug shops in rural Tanzania

Submission date

31/05/2009

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

07/08/2009

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/06/2012

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

N/A

Study information

Scientific Title

The impact of subsidised artemisinin-based combination therapies distributed through private drug shops on consumer uptake and retail price in rural Tanzania: a non-clinical district-randomised controlled trial

Study objectives

The introduction of subsidised artemisinin-based combination therapies (ACTs) at the top of the private sector supply chain will lead to a significant increase in consumer purchase and use of these recommended first-line therapies and a corresponding significant decrease in purchase and use of sub-optimal therapies such as amodiaquine and sulphadoxine-pyramethamine.

The lower price for ACTs offered at the top of the supply chain as a result of the subsidy will result in significantly lower retail prices for these drugs, with consumers paying an equivalent amount as for the most commonly purchased suboptimal therapies.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Tanzania Ministry of Health and Social Welfare approved on the 20th July 2007

Study design

Non-clinical district-randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Malaria

Interventions

A total of four interventions are applied during the project:

1. Provision of ACTs at a price 95% below standard market level to a pharmaceutical wholesaler with agreement to distributed to drug shops
2. Training of drug shop owners and shopkeepers on recognition of malaria symptoms, the importance of use of ACTs as first-line malaria treatment, and proper storage and dispensing practices for ACTs
3. Comprehensive behaviour change communication activities through a variety of media to promote prompt treatment seeking for malaria, demand for and acceptance of ACTs as first-line malaria treatment, and to generate awareness of low-priced ACT in private shops
4. Placement of a suggested retail price on subsidised ACTs distributed through private shops to provide consumers with a clear indication of the appropriate amount to pay for the product

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Proportion of consumers purchasing anti-malarials at private drug shops that buy ACTs. Measured through exit interviews at all shops in target districts at baseline and four surveys during intervention.
2. Price paid for subsidised ACTs and most common alternative anti-malarials by consumers at private drug shops. Measured through exit interviews and the mystery shopper technique at baseline and four times during intervention.
3. The total volume of ACTs distributed by private drug shops in the previous month. Measured through retail audits conducted twice during each survey period (once to establish baseline stock level and follow-up to measure change due to sales), including baseline.

Secondary outcome measures

1. Socioeconomic status of consumers purchasing ACT and other anti-malarials at private drug shops as determined through principal component analysis of household assets. Measured through exit interviews of consumers at baseline and four times during intervention.
2. Volume of ACTs dispensed by all public and nongovernmental health facilities in target districts during preceding month. Measured through audits of public facilities and NGO health facilities at baseline and four times during intervention.
3. Proportion of private drug shops stocking ACTs and alternative anti-malarials. Measured through retail audits at baseline and four times during intervention.
4. Geographic location of drug shops and public/NGO health facilities distributing anti-malarials. Measured through recording of GPS coordinates of all drug shops and facilities during each audit using Garmin Etrex hand units.

Overall study start date

01/11/2007

Completion date

31/12/2009

Eligibility

Key inclusion criteria

All consumers purchasing anti-malarials from a private drug shop (duka la dawa baridi) in target districts (no age or gender restrictions).

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

Greater than 500 per district

Key exclusion criteria

1. Consumers purchasing medicines other than anti-malarials from private drug shops
2. Patients obtaining anti-malarials from other sources, including public health facilities, in the target districts

Date of first enrolment

01/11/2007

Date of final enrolment

31/12/2009

Locations**Countries of recruitment**

Tanzania

United States of America

Study participating centre

383 Dorchester Avenue

Boston

United States of America

02127

Sponsor information**Organisation**

Tanzanian Ministry of Health and Social Welfare (Tanzania)

Sponsor details

National Malaria Control Program
Samora Avenue
P.O. Box 9083
Dar es Salaam
Tanzania
N/A
+255 (0)22 212 0261
ps@moh.go.tz

Sponsor type

Government

Website

<http://www.moh.go.tz/>

ROR

<https://ror.org/03vt2s541>

Funder(s)**Funder type**

Charity

Funder Name

Bill and Melinda Gates Foundation (USA)

Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

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	02/09/2009		Yes	No
Results article	results	02/07/2010		Yes	No