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Responding to the challenge of MERS-CoV: development and testing of interventions to reduce risk among Bedouin populations in Southern Jordan

Submission date
18/09/2024

Recruitment status
No longer recruiting

Registration date
28/11/2024

Overall study status
Completed

Last Edited
28/11/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Middle East respiratory syndrome coronavirus (MERS-CoV) represents one of three deadly zoonotic betacoronaviruses (alongside SARS-CoV and SARS-CoV-2) to have emerged this century. Since initial outbreaks of MERS in Jordan and Saudi Arabia in 2012, ongoing clinical cases continue to occur, almost exclusively within the Arabian Peninsula. More than 2500 laboratory-confirmed cases have now been identified, across 27 countries, though over 80% of cases have been within the Kingdom of Saudi Arabia (KSA). The World Health Organization (WHO) has declared MERS-CoV to be a Blueprint Priority Disease for Research and Development posing a public health risk of epidemic potential, with more than a third of all confirmed cases currently resulting in death. Dromedary camels are the reservoir host for MERS-CoV, with seropositive camels first identified in 2013, in Jordan. Infection in camels is largely sub-clinical, or causing mild upper respiratory signs, while infection in humans ranges from being asymptomatic to causing potentially fatal severe acute respiratory disease. Alongside primary (camel-to-human) transmission, secondary (human-to-human) transmission also occurs, with the potential for large-scale outbreaks, particularly in hospital settings.
To date, MERS-CoV control efforts have largely focused on i) improved camel testing and surveillance strategies, ii) improved triage and biosecurity measures within healthcare settings and iii) vaccine development, though with no commercial vaccines, human or camel, currently available. However, while likely viral transmission routes and high-risk camel engagement activities have now been identified, the potential role of targeted behavioural interventions, aimed at mitigating MERS-CoV exposure among camel-owning communities, has largely been ignored. The aims of this pilot trial are therefore to i) assess the feasibility and effectiveness of employing behavioural interventions in the control of MERS-CoV, and ii) assess potential ability to scale up for wider evaluation in future trials.

Who can participate?
The study will be conducted among camel-owning households in southern Jordan – a 40,000 km2 desert area beside the KSA border. Households will be randomly selected from lists

provided by the Ministry of Agriculture (MoA), and all household members present at the time of the visit will be invited to receive the intervention, except for young children (under 5 years old) and individuals without the capacity to provide informed consent. Household membership will be defined as either i) self-identifying as a household member and sleeping in the household the previous night, or ii) being a household employee.

What does the study involve?
Following a baseline survey of serological status and self-reported practices the planned behavioural interventions have been grouped into 'packages' that address distinct viral transmission pathways and non-communicable disease predisposing to MERS-CoV infection. These packages are as follows:
Package 1. The provision of information regarding the use of face coverings (particularly the traditional 'kaffiyeh') when working with camels, particularly young animals; refraining from kissing camels, particularly young animals; reducing close-quarter exposure to camel crowding (by filling feed and water troughs before allowing camels access); and hand washing after engaging with camels
Package 2. The provision of information regarding improved hand hygiene practices within the home (washing over five times per day with soap)
Package 3. The provision of information regarding the prevention and control of hypertension and diabetes, in accordance with WHO guidelines, in particular regarding smoking, dietary salt intake, dietary sugar intake and physical activity.
Package 4. The provision of information regarding minimizing camel crowding during feeding and watering times through the provision of additional troughs (facilitated by the gifting of one additional trough per five camels in the herd), and closed herd management practices, including quarantining camels (for 3 weeks) entering or re-entering the herd – particularly when used for breeding purposes.
A follow-up telephone call (to the household head) and one follow-up visit to the household home will be conducted 2 and 4 months (respectively) after the initial intervention visits, with the follow-up household visit also used for assessment of outcomes. All visits and telephone calls will be conducted by trained members of an intervention team and will include respected members of the local communities. Households within the control group will also receive the same intervention package as the intervention group, including follow-up visits, after the assessment of intervention uptake among the intervention group has been completed.

What are the possible benefits and risks of participating?
Possible benefits of participating include access to training regarding behavioural interventions with the potential to reduce exposure to MERS-CoV (and potentially serious illness), alongside additional training regarding prevention of important co-morbidities (diabetes and hypertension) and improved hygiene interventions (with the potential to reduce infection from a large range of infectious diseases).
Regarding potential risks or harms in participating, as the interventions are in the form of advice regarding potential behavioural changes (though with minor pain from blood sampling), we expect there to be little potential for harm from the study.

Where is the study run from?
The study is being run by the Royal Veterinary College (RVC) and London School of Hygiene and Tropical Medicine (LSHTM), in partnership with local partners Jordan University of Science and Technology (JUST) and Yarmouk University, Jordan.

When is the study starting and how long is it expected to run for?
October 2020 to February 2025

Who is funding the study?
UK Medical Research Council (MRC), Global Challenges Research Fund

Who is the main contact?
Prof. Javier Guitian, jguitian@rvc.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Javier Guitian

ORCID ID
https://orcid.org/0000-0003-0799-0476

Contact details
Royal College Street
London
United Kingdom
NW1 0TU
+44 (0)20 7468 5000
JGuitian@RVC.AC.UK

Type(s)
Public, Scientific

Contact name
Prof Punam Mangtani

ORCID ID
https://orcid.org/0000-0001-7074-2999

Contact details
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
Punam.Mangtani@lshtm.ac.uk

Type(s)
Scientific

Contact name
Dr Peter Holloway

ORCID ID
https://orcid.org/0000-0001-6648-9724

Contact details
Royal College Street
London
United Kingdom
NW1 0TU
+44 (0)20 7468 5000
pholloway3@rvc.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MR/T02996X/1

Study information

Scientific Title
Effects of a behavioural intervention to reduce MERS-CoV exposure among camel-owning households in southern Jordan: a randomised controlled study

Acronym
MERSJORCT

Study objectives
Targeted behavioural interventions reduce the risk of MERS-CoV exposure among high-risk camel-owning communities

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 01/04/2022, Observational / Interventions Research Ethics Committee, London School of Hygiene & Tropical Medicine (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 26652

2. approved 18/10/2020, Institutional Review Board, King Abdullah University Hospital, Jordan University of Science and Technology (PO Box 630001, Irbid, 22110, Jordan; +962 (0)27200610; irb@kauh.jo), ref: 15/136/2020

3. approved 31/03/2021, Clinical Research Ethical Review Board (CRERB), Royal Veterinary College (Royal College Street, London, NW1 0TU, United Kingdom; +44 (0)20 7468 5300; lwilkinson@rvc.ac.uk), ref: URN 2021 2029-3

Study design

Population-based exploratory blinded parallel individually randomized controlled trial of targeted behavioural interventions

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Middle East Respiratory Syndrome among camel-owning households in Jordan

Interventions
Block randomisation, block size 6, with even numbers assigned to the intervention group, odd numbers to the control group

Primary interventions:

Package 1. Zoonotic camel-to-human MERS-CoV transmission. Intervention includes the provision of information regarding:
1. The use of face coverings (particularly the traditional 'kaffiyeh') when working with camels, particularly young animals
2. Refraining from kissing camels, particularly young animals
3. Reducing close-quarter exposure to camel crowding (by filling feed and water troughs prior to allowing camels access)
4. Hand washing after engaging with camels

Supporting interventions:

Package 2. Secondary human-to-human transmission. Intervention includes the provision of information regarding:
1. Improved hand hygiene practices within the home (washing >5 times per day, with soap)

Package 3. Predisposing comorbidities. Interventions include the provision of information regarding the prevention and control of hypertension and diabetes, in accordance with WHO guidelines, in particular regarding:
3.1. Smoking
3.2. Dietary salt intake
3.3. Dietary sugar intake
3.4. Physical activity

Package 4. Camel-to-camel transmission. Intervention includes the provision of information regarding:
4.1. Minimizing camel crowding during feeding and watering times through the provision of additional troughs (facilitated by the gifting of one additional trough per five camels in the herd)
4.2. Closed herd management practices, including quarantining camels (for 3 weeks) entering or re-entering the herd – particularly when used for breeding purposes

The control group will receive the same intervention package as the intervention group, after any potential impact of the intervention has been assessed among the study population (by

means of self-reported behaviours, observation of behaviours, and serological sampling and laboratory testing by means of MERS-CoV IgG ELISA).

The initial deployment of behavioural interventions among randomly selected households is between September and December 2023, with a telephone call follow-up (to the household head) and follow-up visit conducted approximately 2 months and 4 months after the initial visits, respectively) to reinforce behaviour in the intervention arm.

Intervention Type
Behavioural

Primary outcome(s)
Self-reported and observed behaviours from intervention package 1 (i.e., face-covering when working with camels, avoiding kissing camels, filling troughs before allowing camels access and washing hands after working with camels), quantified as binary outcomes, measured 6 months after delivery if the intervention package

Key secondary outcome(s))
1. Self-reported behaviours quantified as binary outcomes from intervention packages 2 – 4, measured 6 months after delivery if the intervention package
2. Qualitative data regarding intervention uptake, resulting from thematic and discourse analysis of semi-structured interviews, measured 6 months after delivery if the intervention package
3. Serological status on in-house MERS-CoV Spike protein (S1) IgG ELISA, measured 6 months after delivery if the intervention package

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Member of a randomly selected camel-owning household (from Ministry of Agriculture lists) in southern Jordan (Ma'an and Aqaba governorates)

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
5 years

Upper age limit
100 years

Sex

All

Total final enrolment
1200

Key exclusion criteria
1. Children younger than 5 years
2. Individuals without the capacity to provide informed consent

Date of first enrolment
30/09/2022

Date of final enrolment
25/05/2024

Locations

Countries of recruitment
Jordan

Study participating centre
Ministry of Agriculture, Jordan
39 Al Abdullah Street
Amman
Jordan
11181

Sponsor information

Organisation
Royal Veterinary College

ROR
https://ror.org/01wka8n18

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available on request from the corresponding author Dr Peter Holloway (pholloway3@rvc.ac.uk)

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes