

CARRIAGE study: investigating Staphylococcus aureus nasal carriage

Submission date 11/07/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/07/2016	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/12/2025	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Staphylococcus aureus (S. aureus) is a common bacterium with about one person in every three carrying it in their nose, or elsewhere on the skin. Some people carry it all the time, some only now and then, and others never carry it. Currently, we can't explain why. For most people, carriage of S. aureus is harmless. However, a small number of people are susceptible to S. aureus infections due to a weakened immune system and, in some cases, these infections may be serious and resistant to antibiotic treatment. Understanding why only some people are carriers while others aren't will help design new ways to prevent and treat such infections. The aim of this study is to investigate why some people carry S. aureus in their nose while others never do. The study will provide a better understanding of the biological, genetic and environmental factors that determine S. aureus carriage. One way to see if a person carries S. aureus is to analyse swabs taken from the nose.

Who can participate?

Healthy volunteers who participated in the, INTERVAL, COMPARE, and STRIDES BioResource (part of the NIHR BioResource) studies.

What does the study involve?

In phase 1, 250 participants are randomly allocated to one of two swabbing frequencies (two versus three swabs). The acceptability of each swabbing frequency is assessed based on participant response rates and participant feedback from an online questionnaire asking about experiences of taking part in the study.

In phase 2 a further 2000 participants are invited to collect nasal swabs. The number of swabs collected is informed by the results of phase 1 (i.e., either two or three). This phase assesses the feasibility of collecting, processing and analysing swabs from large numbers of participants. In phase 3, participants from the INTERVAL, COMPARE and STRIDES BioResource studies are invited to collect three nasal swabs so that we receive a full sample set from 20,000 participants in total. This is the phase which follows on from phase 1 and is an extension of phase 2 which tested the feasibility of the study design.

What are the possible benefits and risks of participating?

We will not provide any new information or advice to participants based on the samples and

data collected during the study; at present, this information has no clinical implications for the participant. As such, involvement in the study will have no direct benefit to participants. However, it is an opportunity for volunteers to support research, which addresses an important public health issue. There are no known risks associated with nasal swabbing. All participants will receive clear written instructions and a link to an online video demonstrating swabbing technique. Nasal swabbing may pose minor risks in individuals with nasal problems or nasal damage and, as such, potential participants who report having such conditions will be excluded from the study.

Where is the study run from?

The study is coordinated by the University of Cambridge and is conducted in the community across England.

When is the study starting and how long is it expected to run for?

September 2016 to September 2023

Who is funding the study?

1. Wellcome Trust
2. UK Research and Innovation (UKRI)
3. Health Data Research (HDR) UK
4. The Isaac Newton Trust

Who is the main contact?

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Integrated Research Application System (IRAS)

202688

Protocol serial number

Protocol version 4 - 20/06/2018

Study information

Scientific Title

Understanding the biological basis of persistent carriage of Staphylococcus aureus in humans

Acronym

CARRIAGE

Study objectives

The principal research question is to assess the feasibility and acceptability of protocols for the collection and processing of nasal self-swabs in healthy volunteers to inform a larger proposed study to investigate the biological basis of persistent Staphylococcus aureus (*S. aureus*) carriage.

The secondary research objectives are to assess:

1. The relative participant-acceptability of two vs three weekly nasal swabs
2. The prevalence of persistent *S. aureus* carriage rates in healthy volunteers
3. Lifestyle and biomarker correlates of persistent nasal carriage and validate associations with previously suggested candidate variants, and to identify new genetic associations (added 19/06/2019)

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West - Lancaster Research Ethics Committee, 27/06/2016, REC reference: 16/NW/0507, IRAS project ID: 202688

Study design

Two-stage feasibility study with interventional, observational and cross-sectional components followed by the main study phase

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Nasal carriage of Staphylococcus aureus

Interventions

Current interventions as of 24/02/2023:

Phase 1 and 2 of the study will involve the recruitment of participants who have taken part in previous studies (INTERVAL: ISRCTN24760606) and have agreed to be invited to other studies organised by NHS Blood and Transplant and/or University of Cambridge and/or University of Oxford.

Phase 3 (main study) will, in addition to INTERVAL, include participants from the COMPARE study (ISRCTN90871183) and STRIDES BioResource study.

In phase 1: Participant acceptability of collecting two versus three swabs will be compared in approximately 250 participants (125 per arm). Prior to invitation, there will be a 1:1 random allocation to each of the swabbing frequencies; simple block randomisation stratified by age and gender will be used. The acceptability of each protocol will be based on participant response rates to the two- and three-swab protocol and participant feedback from an online questionnaire asking about experiences of taking part in the study – now complete.

Phase 2: A further (approximately) 2000 participants will be invited to collect nasal swabs. The number of swabs collected will be informed by the results of phase 1 (i.e. either two or three). This phase will assess, more generally, the operational feasibility of collecting, processing and analysing swabs in large numbers of participants. It will also assess lifestyle and biomarker correlates of persistent nasal *S. aureus* carriage. – now complete.

In Phase 3: This is the main study phase where we will consent enough participants to retrieve a full sample set (3 swabs) from 20,000 participants. . This phase will assess, more generally, the operational feasibility of collecting, processing and analysing swabs in large numbers of participants. It will also assess lifestyle and biomarker correlates of persistent nasal *S. aureus* carriage and to identify new genetic associations.

In all phases of the study prevalence rates of *S. aureus* carriage will be assessed.

Participants joining the study will be asked to complete an online baseline questionnaire designed to collect health and lifestyle information which may be relevant to predisposition to *S. aureus* carriage. On completion of their questionnaire, participants will be sent a nasal swabbing pack in the post and asked to return their first swab immediately and subsequent swabs at weekly intervals. Once participants have returned all swabs they will be sent an online feedback questionnaire about their experiences of taking the swabs and participating in the study.

The study will be administered by the University of Cambridge and will be conducted in the community across England.

Previous interventions as of 19/06/2019:

Phase 1 and 2 of the study will involve the recruitment of participants who have taken part in previous studies (INTERVAL: ISRCTN24760606) and have agreed to be invited to other studies organised by NHS Blood and Transplant and/or University of Cambridge and/or University of Oxford.

Phase 2 (extended) (main study) will, in addition to INTERVAL, include participants from the COMPARE study (ISRCTN90871183).

In phase 1: Participant acceptability of collecting two versus three swabs will be compared in approximately 250 participants (125 per arm). Prior to invitation, there will be a 1:1 random allocation to each of the swabbing frequencies; simple block randomisation stratified by age and gender will be used. The acceptability of each protocol will be based on participant response rates to the two- and three-swab protocol and participant feedback from an online questionnaire asking about experiences of taking part in the study – now complete.

Phase 2: A further (approximately) 2000 participants will be invited to collect nasal swabs. The number of swabs collected will be informed by the results of phase 1 (i.e. either two or three). This phase will assess, more generally, the operational feasibility of collecting, processing and analysing swabs in large numbers of participants. It will also assess lifestyle and biomarker correlates of persistent nasal *S. aureus* carriage. – now complete.

In Phase 2 (extended): This is the main study phase where approximately 20,000 participants will be invited to take part. This phase will assess, more generally, the operational feasibility of collecting, processing and analysing swabs in large numbers of participants. It will also assess lifestyle and biomarker correlates of persistent nasal *S. aureus* carriage and to identify new genetic associations.

In all phases of the study prevalence rates of *S. aureus* carriage will be assessed.

Participants joining the study will be asked to complete an online baseline questionnaire designed to collect health and lifestyle information which may be relevant to predisposition to *S. aureus* carriage. On completion of their questionnaire, participants will be sent a nasal swabbing pack in the post and asked to return their first swab immediately and subsequent swabs at weekly intervals. Once participants have returned all swabs they will be sent an online feedback questionnaire about their experiences of taking the swabs and participating in the study.

The study will be administered by the University of Cambridge and will be conducted in the community across England.

Previous interventions:

Both stages of the study will involve the recruitment of participants who have taken part in a previous study (INTERVAL: ISRCTN24760606) and have agreed to be invited to other studies organised by NHS Blood and Transplant and/or University of Cambridge and/or University of Oxford.

In stage 1: Participant acceptability of collecting two versus three swabs will be compared in approximately 250 participants (125 per arm). Prior to invitation, there will be a 1:1 random allocation to each of the swabbing frequencies; simple block randomisation stratified by age and gender will be used. The acceptability of each protocol will be based on participant response rates to the two- and three-swab protocol and participant feedback from an online questionnaire asking about experiences of taking part in the study.

In Stage 2: A further (approximately) 2000 participants will be invited to collect nasal swabs. The number of swabs collected will be informed by the results of Stage 1 (i.e. either two or three). This stage will assess, more generally, the operational feasibility of collecting, processing and analysing swabs in large numbers of participants. It will also assess lifestyle and biomarker correlates of persistent nasal *S. aureus* carriage.

In both stages of the study prevalence rates of *S. aureus* carriage will be assessed.

Participants joining the study will be asked to complete an online baseline questionnaire designed to collect health and lifestyle information which may be relevant to predisposition to *S. aureus* carriage. On completion of their questionnaire, participants will be sent a nasal swabbing pack in the post and asked to return their first swab immediately and subsequent swabs at weekly intervals. Once participants have returned all swabs they will be sent an online feedback questionnaire about their experiences of taking the swabs and participating in the study.

The study will be administered by the University of Cambridge and will be conducted in the community across England.

Intervention Type

Other

Primary outcome(s)

Current primary outcome measure as of 19/06/2019:

1. To assess the feasibility of collecting, processing and analysing nasal swabs in large numbers of participants.
2. To assess the prevalence of persistent *S. aureus* nasal carriage rates in healthy volunteers.
3. To assess lifestyle and biomarker correlates of persistent nasal *S. aureus* carriage and validate associations with previously suggested candidate genetic variants and to identify new genetic associations.

Previous primary outcome measure:

Response rates to nasal swab collections including differences in response rates to initial invitation to provide two vs three swabs and compliance to the collection and return of two vs three swabs

Key secondary outcome(s)

Current secondary outcome measures as of 27/02/2023:

Phases 1 & 2:

1. Participant feedback from the online questionnaire administered to participants on completion of their involvement in the study. Data collected will include binary (yes/no), Likert Scale and free text responses
2. Operational outcomes: the success of operational procedures will be reviewed including: posting of nasal swabbing packs, sample receipt at the processing laboratory and laboratory methods for sample processing and analysis

Phase 3

1. To assess the feasibility of collecting, processing and analysing nasal swabs in large numbers of participants.
2. To assess the prevalence of persistent *S. aureus* nasal carriage rates in healthy volunteers.
3. To assess lifestyle and biomarker correlates of persistent nasal *S. aureus* carriage and validate associations with previously suggested candidate genetic variants and to identify new genetic associations.

Previous secondary outcome measures as of 19/06/2019:

Phases 1 & 2:

1. Participant feedback from the online questionnaire administered to participants on completion of their involvement in the study. Data collected will include binary (yes/no), Likert Scale and free text responses
2. Operational outcomes: the success of operational procedures will be reviewed including: posting of nasal swabbing packs, sample receipt at the processing laboratory and laboratory methods for sample processing and analysis

Previous secondary outcome measures:

Stages 1 & 2:

1. Participant feedback from the online questionnaire administered to participants on completion of their involvement in the study. Data collected will include binary (yes/no), Likert Scale and free text responses
2. Prevalence of persistent nasal carriage of *Staphylococcus aureus* in healthy volunteers. The point prevalence of carriage will be calculated using the first swabs returned by participants. Persistent carriage will be defined based on two positive swabs in participants randomised to the two-swab protocol and three positive swabs in participants randomised to the three-swab protocol.
3. Operational outcomes: the success of operational procedures will be reviewed including: posting of nasal swabbing packs, sample receipt at the processing laboratory and laboratory methods for sample processing and analysis

Stage 2:

Lifestyle, biomarker and genetic correlates of persistent *S. aureus* carriage assessed using either logistic or linear regression models

Completion date

27/06/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 24/02/2023:

1. Be already enrolled in the INTERVAL, COMPARE or STRIDES BioResource studies
2. Have an email address for study participation
3. Reside in mainland England
4. Have a good understanding of the English language, both written and oral (study materials are not tailored to support non-English language speakers)

Previous participant inclusion criteria as of 19/06/2019:

1. Be already enrolled in the INTERVAL or COMPARE studies
2. Have an email address for study participation
3. Reside in mainland England
4. Have a good understanding of the English language, both written and oral (study materials are not tailored to support non-English language speakers)

Previous participant inclusion criteria:

1. Be already enrolled in the INTERVAL study
2. Have an email address for study participation
3. Reside in mainland England
4. Have a good understanding of the English language, both written and oral (study materials are not tailored to support non-English language speakers)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

0

Key exclusion criteria

Current exclusion criteria as of 24/02/2023:

1. Received three invitations from the INTERVAL, COMPARE or STRIDES BioResource research study teams to take part in other studies in the past year
2. Withdrawn their consent to take part in the INTERVAL, COMPARE or STRIDES BioResource studies
3. Any abnormalities or ongoing medical conditions that affect the nose (e.g. nosebleeds, nasal polyps, rhinitis, etc)
4. Undergone nasal surgery in the last year
5. Nasal fracture in the last year

Previous participant exclusion criteria as of 19/06/2019:

1. Received three invitations from the INTERVAL or COMPARE research study teams to take part in other studies in the past year
2. Withdrawn their consent to take part in the INTERVAL or COMPARE studies
3. Any abnormalities or ongoing medical conditions that affect the nose (e.g. nosebleeds, nasal

polyps, rhinitis, etc)

4. Undergone nasal surgery in the last year

5. Nasal fracture in the last year

Previous participant exclusion criteria:

1. Have received 3 invitations from the INTERVAL research study team to take part in other studies in the past year

2. Have withdrawn their consent to take part in the INTERVAL study

3. Have any abnormalities or ongoing medical conditions that affect the nose (e.g. nosebleeds, nasal polyps, rhinitis, etc)

4. Have undergone nasal surgery in the last year

5. Have had a nasal fracture in the last year

6. Are not going to be available to take part in the study during the next two months due to reasons such as an extended holiday

Date of first enrolment

19/09/2016

Date of final enrolment

31/12/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Cambridge

Department of Medicine

Box 157, level 5

Addenbrooke's Hospital

Hills Road

Cambridge

England

CB2 0QQ

Study participating centre

University of Cambridge

Dept Public Health and Primary Care

Heart and Lung Research Institute

Papworth Road

Cambridge

England
CB2 0BB

Sponsor information

Organisation

University of Cambridge (UK)

ROR

<https://ror.org/013meh722>

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

UK Research and Innovation

Alternative Name(s)

UKRI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Health Data Research (HDR) UK

Funder Name

Isaac Newton Trust

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications		02/12/2025	03/12/2025	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes