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Understanding how the immune system responds to repeated malaria infections

Submission date 03/11/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/11/2023	**Overall study status** Ongoing	
Last Edited 30/05/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Malaria is an infectious disease caused by the Plasmodium parasite and is a major public health problem in many parts of the world. Malaria is spread by the bite of an infected mosquito. There are five species of the Plasmodium parasite that are known to cause malaria in humans. Of these five species, Plasmodium falciparum causes the most sickness and death globally, with an estimated 241 million cases of malaria and 619,000 deaths worldwide in 2021. Plasmodium vivax accounts for more than half of all malaria cases in the Americas and Southeast Asia; globally, around 14 million annual cases present a significant clinical and economic burden. Most of the deaths from malaria occur in children under five living in Africa, with infants under 1 year being at the highest risk.

A significant study conducted in Tanzania showed that while the number of malaria parasites in the blood remained constant over the first few malaria infections of life, the risk of severe disease and hospitalisation decreased significantly with each infection. This study concluded that rather than killing the malaria parasite, the immune system developed the ability to 'tolerate' the presence of the parasite in the body, which reduced the damage caused during repeated infections. This was an important finding, however, the way that the immune system tolerates the malaria parasite remains unknown.

In order to better understand how the immune system adapts to tolerate the malaria parasite after repeated infections, this study will recruit participants to undergo three malaria challenges. In a 'malaria challenge', study participants will be injected with a small amount of malaria-infected blood under carefully regulated conditions to cause malaria infection. This is important as the exact moment of infection will be known making it possible to track the immune response that follows. This is difficult to do when studying infections that occur naturally.

This study will assess:
1. Changes in the immune (T-cell) response after three infections with P. falciparum malaria (Group 1 only)
2. Changes in the immune (T-cell) response after two infections with P. falciparum malaria followed by one infection with a different species of malaria, P. vivax (Group 2 only)

3. Changes in the bone marrow following the first malaria infection (Group 2 only) compared to the third malaria infection (Group 1 only) (we will do this by taking samples of bone marrow through a procedure called a 'bone marrow test')
4. Whether the immune (T-cell) response to vaccination is changed by repeated malaria infection – we will use the yellow fever vaccine to answer this question as this vaccine is known to stimulate a T-cell response.

While the main aim of our study is to improve malaria survival among children in areas of the world where malaria is common, there are a number of reasons why this study was undertaken in healthy adults in the UK. Firstly, in areas of the world where malaria is common, it would be difficult to find adults who have not had malaria before. This is important to understand the difference in the immune response to the first-ever malaria infection and malaria infections that occur afterwards. Additionally, this type of research could not be conducted in infants as it would not be possible or ethical to take the amount of blood needed for the laboratory tests from young children. It is hoped that the results of this study will help inform strategies to reduce the frequency of severe disease and death among children in parts of the world where the burden of malaria is high.

Who can participate?
Healthy adults aged 18–45 years old

What does the study involve?
Participants will enrol into either Group 1, Group 2 or Group 3
Group 1: Participants will undergo three malaria challenges, approximately 5 months apart. After the third (and last) malaria challenge, they will be asked to drink a small amount of a substance called heavy water daily for between 2-3 weeks. They will also undergo a bone marrow test. They will then receive the yellow fever vaccination and complete their follow-up visits. The total study time will be around 20 months (plus 2 later optional visits occurring 3 and 15 months later)
Group 2: Participants will receive the yellow fever vaccination first and then undergo three malaria challenges, approximately 5 months apart. After the first malaria challenge, they will be asked to drink a small amount of a substance called heavy water daily for between 2–3 weeks. They will also undergo a bone marrow test. They will then complete their follow-up visits. The total study time will be around 20 months.

Group 3 will undergo a bone marrow test only. The purpose of this group is to provide healthy bone marrow samples for comparison with Group 1 and Group 2.

What are the possible benefits and risks of participating?
Benefits: Participating in this study will not provide a direct benefit. It will help our research into changes in the immune response to malaria after repeated infections. A better understanding of this may help us develop more effective strategies to reduce the global burden of malaria disease and malaria deaths.
Risks: Untreated malaria infection can result in serious illness, therefore it is crucial that participants attend all follow-up visits and take the anti-malarial treatment as advised. Short-lived post-vaccination symptoms such as arm pain and fever may occur. There is also a small risk of pain, bleeding and infection following a bone marrow test. We will monitor the safety of all participants closely.

Where is the study run from?
Centre for Clinical Vaccinology and Tropical Medicine (CCVTM) and Oxford Experimental Medicine Clinical Research Facility (EMCRF), Churchill Hospital, Oxford (UK)

When is the study starting and how long is it expected to run for?
March 2022 to November 2027

Who is funding the study?
The study is organised by the University of Oxford (UK) and is funded by an Experimental Medicine grant from the UK Medical Research Council (MRC) (UK)

Who is the main contact?
Volunteer Recruitment Co-ordinator, info@ovg.ox.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
330788

Central Portfolio Management System (CPMS)
58892

Protocol serial number
MR/X005321/1

Study information

Scientific Title
BIO-004: Reprogramming T cells for disease tolerance in falciparum malaria

Acronym
BIO-004

Study objectives
This study will assess:
1. Changes in the immune (T-cell) response after three infections with P. falciparum malaria (G1 only)
2. Changes in the immune (T-cell) response after two infections with P. falciparum malaria followed by one infection with a different species of malaria, P. vivax (G2 only)
3. Changes in the bone marrow following the first malaria infection (2) compared to the third malaria infection (G1) (we will do this by taking a sample of bone marrow through a procedure called a “bone marrow test”)
4. Whether the immune (T-cell) response to vaccination is changed by repeated malaria infection – we will use the licenced yellow fever vaccine, Stamaril, to answer this question as this vaccine is known to stimulate a T-cell response.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/11/2023, South Central - Berkshire REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8178, (0)207 104 8182, (0)207 104 8233; berkshire.rec@hra.nhs.uk), ref: 23/SC/0364

Primary study design
Interventional

Study design
Interventional non-randomized study

Study type(s)
Other

Health condition(s) or problem(s) studied
P. falciparum malaria

Interventions

Current interventions as of 28/03/2025:

We will recruit 25-27 participants for three study groups.

Group 2 participants will receive the yellow fever vaccination first. Approximately four months after this, they will undergo three malaria challenges, each approximately 5 months apart. The first two challenges will be with a strain of Plasmodium falciparum malaria (Pf3D7) and the third challenge will be with a strain of Plasmodium vivax malaria (PvW1) or a strain of Plasmodium falciparum malaria (Pf3D7). Seven days after the first malaria challenge, Group 2 participants will be asked to drink a small amount of a substance called ‘heavy water’ daily for between 2-3 weeks to allow us to "track" the T cell response to infection more closely. Additionally, 3-7 days after commencing antimalarial treatment after the first malaria challenge, Group 2 participants will also undergo a bone marrow test (aspiration and trephine biopsy). The total study time for Group 2 participants will be around 20 months.

Group 1 participants will first undergo three malaria challenges with Plasmodium falciparum malaria (Pf3D7), each approximately 5 months apart (all study participants will be challenged on the same day to ensure comparability between groups). Seven days after the third (and last) malaria challenge, Group 1 participants will be asked to drink a small amount of a substance called ‘heavy water’ daily for between 2-3 weeks in order to label their T cells. These participants will then undergo a bone marrow test 3-7 days after commencing antimalarial treatment after their third malaria challenge. Approximately four months after the third and final malaria challenge, Group 1 participants will then receive the yellow fever vaccination and complete follow-up visits. The total study for Group 1 participants will be around 20 months (plus 2 optional visits occurring 3 and 15 months later).

Group 3 will undergo a bone marrow test only. The purpose of this group is to provide healthy bone marrow samples for comparison with Group 1 and Group 2.

Primary Objectives
1. To model the infection dynamics and assess changes in parasite multiplication rate (PMR) through primary, secondary and tertiary blood-stage CHMI with P. falciparum
2. To measure the proliferation rate and half-life of total and YFV-specific memory T cells during and after blood-stage CHMI with P. falciparum

Secondary Objectives
1. To assess the feasibility and safety of heterologous P. vivax challenge after blood-stage CHMI with P. falciparum
2. To measure the immune response to P. vivax by induction of parasite-specific class-switched antibodies

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Previous interventions:

We will recruit 22 participants for two study groups (11 participants per group).

Group 2 participants will receive the yellow fever vaccination first. Approximately four months after this, they will undergo three malaria challenges, each approximately 5 months apart. The first two challenges will be with a strain of Plasmodium falciparum malaria (Pf3D7) and the third challenge will be with a strain of Plasmodium vivax malaria (PvW1). Seven days after the first

malaria challenge, Group 2 participants will be asked to drink a small amount of a substance called ‘heavy water’ daily for between 2-3 weeks to allow us to "track" the T cell response to infection more closely. Additionally, 3-7 days after commencing antimalarial treatment after the first malaria challenge, Group 2 participants will also undergo a bone marrow test (aspiration and trephine biopsy). The total study time for Group 2 participants will be around 20 months.

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Primary Objectives
1. To model the infection dynamics and assess changes in parasite multiplication rate (PMR) through primary, secondary and tertiary blood-stage CHMI with P. falciparum
2. To measure the proliferation rate and half-life of total and YFV-specific memory T cells during and after blood-stage CHMI with P. falciparum

Secondary Objectives
1. To assess the feasibility and safety of heterologous P. vivax challenge after blood-stage CHMI with P. falciparum
2. To measure the immune response to P. vivax by induction of parasite-specific class-switched antibodies

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Yellow fever vaccine, Plasmodium falciparum malaria (Pf3D7) vaccine, Plasmodium vivax malaria (PvW1) vaccine

Primary outcome(s)
1. Parasite growth rate measured using plasmodium falciparum-specific 18S rRNA qPCR assay and linear modelling for parasite multiplication rate (PMR)
2. Proliferation rate and half-life of total and Yellow fever vaccine (YFV)-specific memory T cells measured using flow cytometry with cell sorting and mass spectrometry analysis of deuterium incorporation

Key secondary outcome(s)
1. Pan-Plasmodium 18S rRNA qPCR assay for confirmation of successful infection together with active and passive detection of (S)AE
2. Anti-PvDBPII total IgG standardised ELIS

Exploratory Immunology Objectives
Any other immunological analyses performed will be reported as not pre-specified in the study protocol. Other analyses may be detailed in the BIO-004 laboratory plan. Some assays may be duplicated at different laboratory sites. Some of these will involve analysis of frozen samples, and others analysis of fresh samples.
For any exploratory endpoints not completed prior to the end of the study, where appropriate consent is received, samples will be registered under the University of Oxford HTA licence 12217 and analysed under the University of Oxford's Central University Research Ethics Committee (CUREC) ethical approval.
Exploratory immunology objectives include (but are not limited to):
1. Assessing whether T cell activation is pathogenic during a first-in-life malaria episode
2. Identifying the cellular and molecular adaptations that reprogram activated T cells
3. Measuring the functional capacity of T cells to provide essential B cell help

Exploratory Immunology Outcome Measures
Possibilities for exploratory immunology include (but are not limited to):
1. Tetramer and intracellular cytokine staining of memory T cells (ex vivo) by CyTOF.
2. Flow sorting and mass spectrometry of activated T cells.
3. IgG+/IgM+ memory B cell differentiation in organoid cultures.
4. Bead-based plasma protein arrays.
5. ChIP-sequencing and culture-based assays (such as cytoadherence and cytotoxicity) using cryopreserved PBMC.
6. High dimensional imaging mass cytometry of bone marrow biopsies.

Other established and exploratory immunology assays may be carried out, which may include collaboration with other specialist laboratories within or beyond Europe. This would involve the transfer of samples, but samples would be pseudonymised. Volunteers will provide consent for this.

Completion date
30/11/2027

Eligibility

Key inclusion criteria
Participant inclusion criteria as of 30/04/2024:

1. Healthy, malaria-naïve adult aged 18 to 45 years old
2. Able and willing (in the Investigator's opinion) to comply with all study requirements
3. Willing to allow the Investigators to access the volunteer's electronic medical records or discuss the volunteer's medical history with their GP
4. Participants of childbearing potential only: must practice continuous effective contraception for the duration of the study
5. Able and willing to provide written informed consent to participate in the trial
6. Negative haemoglobinopathy screen (including sickle cell disease and alpha and beta thalassaemia) and normal G6PD levels
7. Agreement to permanently refrain from blood donation during and after the study, as per current UK Blood Transfusion and Tissue Transplantation Services guidelines
8. Reachable (24 hours a day) by mobile phone during the period between CHMI and completion of anti-malarial treatment
9. Willing to take a curative anti-malarial treatment regimen following CHMI

10. Able to answer all questions on the informed consent questionnaire correctly at the first or second attempt
11. Able to travel to CCVTM
12. Willingness to be registered on the TOPS database (The Overvolunteering Prevention System; www.tops.org.uk).

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Previous participant inclusion criteria:

1. Healthy, malaria-naïve, CMV-seropositive adult aged 18 to 45 years old
2. Able and willing (in the Investigator's opinion) to comply with all study requirements
3. Willing to allow the Investigators to access the volunteer's electronic medical records or discuss the volunteer's medical history with their GP
4. Participants of childbearing potential only: must practice continuous effective contraception for the duration of the study
5. Able and willing to provide written informed consent to participate in the trial
6. Negative haemoglobinopathy screen (including sickle cell disease and alpha and beta thalassaemia) and normal G6PD levels
7. Agreement to permanently refrain from blood donation during and after the study, as per current UK Blood Transfusion and Tissue Transplantation Services guidelines
8. Reachable (24 hours a day) by mobile phone during the period between CHMI and completion of anti-malarial treatment
9. Willing to take a curative anti-malarial treatment regimen following CHMI
10. Able to answer all questions on the informed consent questionnaire correctly at the first or second attempt
11. Able to travel to CCVTM
12. Willingness to be registered on the TOPS database (The Overvolunteering Prevention System; www.tops.org.uk).

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

Total final enrolment
27

Key exclusion criteria

Participant exclusion criteria as of 30/04/2024:

1. Red blood cells negative for the Duffy antigen/chemokine receptor (DARC) (this exclusion criterion is for Group 2 only)
2. Body weight < 50 kg or Body Mass Index (BMI) < 18.0 at screening
3. History of clinical malaria (any species) or previous participation in any malaria vaccine trial or CHMI
4. History of yellow fever virus infection or prior receipt of YFV
5. Travel to a clearly malaria endemic locality during the study period or within the preceding six months
6. Use of immunoglobulins or blood products (e.g. blood transfusion) in the last three months
7. Receipt of any vaccine (except the COVID-19 vaccine or flu) in the 30 days preceding enrolment, or planned receipt during the study period
8. Receipt of a COVID-19 or flu vaccine within 2 weeks before the day of CHMI or planned receipt of a COVID-19 or flu vaccine prior to expected completion of anti-malarial treatment (around 2 to 3 weeks after day of challenge based on experience in previous P. falciparum CHMI studies to date)
9. Receipt of an investigational product in the 30 days preceding enrolment, or planned receipt during the study period
10. Concurrent involvement in another clinical trial involving an investigational product or planned involvement during the study period
11. Any confirmed or suspected immunosuppressive or immunodeficient state, including HIV infection; asplenia; recurrent, severe infections and chronic (more than 14 days) immunosuppressant medication within the past 6 months (inhaled and topical steroids are allowed)
12. Previous thymectomy or known or suspected thymic disorder
13. Hypersensitivity reactions to eggs, chicken proteins or any component of Stamaril
14. Any history of anaphylaxis in reaction to vaccinations
15. Any confirmed or suspected bleeding disorders
16. Current use of anticoagulant medication e.g. low molecular weight heparin, warfarin, apixaban, edoxaban
17. Known allergy to local anaesthetics e.g. lidocaine
18. Use of systemic antibiotics with known anti-malarial activity within 30 days of CHMI (e.g. trimethoprim-sulfamethoxazole, doxycycline, tetracycline, clindamycin, erythromycin, fluoroquinolones and azithromycin)
19. Use of anti-malarials within 30 days of CHMI
20. Any clinical condition known to prolong the QT interval
21. History of cardiac arrhythmia, including clinically relevant bradycardia
22. Disturbances of electrolyte balance, e.g. hypokalaemia or hypomagnesaemia
23. Family history of congenital QT prolongation or sudden death
24. An estimated ten-year risk of fatal cardiovascular disease of > = 5% at screening, as determined by the Systematic Coronary Risk Evaluation (SCORE) shown in Appendix B in the protocol
25. Use of medications known to have a potentially clinically significant interaction with Riamet
26. Any other contraindications/known hypersensitivities to Riamet or Malarone
27. History of sickle cell anaemia, sickle cell trait, thalassaemia or thalassaemia trait, G6PD deficiency or any haematological condition that could affect susceptibility to malaria infection
28. Pregnancy, lactation or intention to become pregnant during the study
29. History of cancer (except basal cell carcinoma of the skin and cervical carcinoma in situ)
30. History of serious psychiatric condition that may affect participation in the study

31. Any other serious chronic illness requiring hospital specialist supervision
32. Suspected or known current alcohol misuse as defined by an alcohol intake of greater than 25 standard UK units every week
33. Suspected or known injecting drug use in the 5 years preceding enrolment
34. Hepatitis B surface antigen (HBsAg) detected in serum
35. Seropositive for hepatitis C virus (antibodies to HCV) at screening (unless volunteer has taken part in a prior hepatitis C vaccine study with confirmed negative HCV antibodies prior to participation in that study, and negative HCV ribonucleic acid (RNA) PCR at screening for this study)
36. Volunteers are unable to be closely followed for social, geographic or psychological reasons
37. Any clinically significant abnormal finding on biochemistry or haematology blood tests, or clinical examination. The normal range of results for each blood parameter is shown in Table 19 (Appendix A of the study protocol). In the event of abnormal test results, confirmatory repeat tests will be requested. Procedures for identifying laboratory values meeting exclusion criteria are described in Appendix A.
38. Any other significant disease, disorder, or finding which may significantly increase the risk to the volunteer because of participation in the study, affect the ability of the volunteer to participate in the study or impair interpretation of the study data
39. Inability of the study team to confirm medical history via electronic records or contact the volunteer's GP to confirm medical history

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Previous participant exclusion criteria:

1. CMV-negative serostatus
2. Red blood cells negative for the Duffy antigen/chemokine receptor (DARC) (this exclusion criterion is for Group 2 only)
3. Body weight < 50 kg or Body Mass Index (BMI) < 18.0 at screening
4. History of clinical malaria (any species) or previous participation in any malaria vaccine trial or CHMI
5. History of yellow fever virus infection or prior receipt of YFV
6. Travel to a clearly malaria endemic locality during the study period or within the preceding six months
7. Use of immunoglobulins or blood products (e.g. blood transfusion) in the last three months
8. Receipt of any vaccine (except the COVID-19 vaccine or flu) in the 30 days preceding enrolment, or planned receipt during the study period
9. Receipt of a COVID-19 or flu vaccine within 2 weeks before the day of CHMI or planned receipt of a COVID-19 or flu vaccine prior to expected completion of anti-malarial treatment (around 2 to 3 weeks after day of challenge based on experience in previous P. falciparum CHMI studies to date)
10. Receipt of an investigational product in the 30 days preceding enrolment, or planned receipt during the study period
11. Concurrent involvement in another clinical trial involving an investigational product or planned involvement during the study period
12. Any confirmed or suspected immunosuppressive or immunodeficient state, including HIV infection; asplenia; recurrent, severe infections and chronic (more than 14 days) immunosuppressant medication within the past 6 months (inhaled and topical steroids are allowed)
13. Previous thymectomy or known or suspected thymic disorder
14. Hypersensitivity reactions to eggs, chicken proteins or any component of Stamaril
15. Any history of anaphylaxis in reaction to vaccinations

16. Any confirmed or suspected bleeding disorders
17. Current use of anticoagulant medication e.g. low molecular weight heparin, warfarin, apixaban, edoxaban
18. Known allergy to local anaesthetics e.g. lidocaine
19. Use of systemic antibiotics with known anti-malarial activity within 30 days of CHMI (e.g. trimethoprim-sulfamethoxazole, doxycycline, tetracycline, clindamycin, erythromycin, fluoroquinolones and azithromycin)
20. Use of anti-malarials within 30 days of CHMI
21. Any clinical condition known to prolong the QT interval.
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24. Family history of congenital QT prolongation or sudden death.
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27. Any other contraindications/known hypersensitivities to Riamet or Malarone
28. History of sickle cell anaemia, sickle cell trait, thalassaemia or thalassaemia trait, G6PD deficiency or any haematological condition that could affect susceptibility to malaria infection
29. Pregnancy, lactation or intention to become pregnant during the study
30. History of cancer (except basal cell carcinoma of the skin and cervical carcinoma in situ)
31. History of serious psychiatric condition that may affect participation in the study
32. Any other serious chronic illness requiring hospital specialist supervision
33. Suspected or known current alcohol misuse as defined by an alcohol intake of greater than 25 standard UK units every week
34. Suspected or known injecting drug use in the 5 years preceding enrolment
35. Hepatitis B surface antigen (HBsAg) detected in serum
36. Seropositive for hepatitis C virus (antibodies to HCV) at screening (unless volunteer has taken part in a prior hepatitis C vaccine study with confirmed negative HCV antibodies prior to participation in that study, and negative HCV ribonucleic acid (RNA) PCR at screening for this study)
37. Volunteers are unable to be closely followed for social, geographic or psychological reasons.
38. Any clinically significant abnormal finding on biochemistry or haematology blood tests, or clinical examination. The normal range of results for each blood parameter is shown in Table 19 (Appendix A of the study protocol). In the event of abnormal test results, confirmatory repeat tests will be requested. Procedures for identifying laboratory values meeting exclusion criteria are described in Appendix A.
39. Any other significant disease, disorder, or finding which may significantly increase the risk to the volunteer because of participation in the study, affect the ability of the volunteer to participate in the study or impair interpretation of the study data
40. Inability of the study team to confirm medical history via electronic records or contact the volunteer’s GP to confirm medical history

Date of first enrolment
22/12/2023

Date of final enrolment
29/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
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OX3 7LE

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory 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 data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

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