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Pilot study investigating the efficiency and effectiveness of a clinic that is designed to remove penicillin allergy from low-risk patients who believe they are allergic to penicillin

Submission date 06/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/02/2023	**Overall study status** Completed	
Last Edited 11/03/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Penicillin was one of the first antibiotics used to treat bacterial infections. This medication is still the most effective way to treat many of these different infections. There are a high number of people who are labelled with a penicillin allergy (up to 15% of the population). This is more than any other medication. Many people who believe that they are allergic to penicillin are not and can safely take it. This is important because penicillin is the best treatment for many bacterial infections. Using the best treatment for bacterial infections reduces the number of new infections caused by bacteria that are harder to treat with other antibiotics. Direct Oral Challenge is a safe way to remove a mislabeled allergy. Several studies in larger academic centers have already been conducted. These studies confirm that DOC is a safe replacement for skin testing in low-risk adults. In this study a direct oral challenge clinic is being set up and evaluated at Muskoka Algonquin Healthcare (MAHC).

Who can participate?
Participants over 18 years old who are labelled with (or believe they have) an allergy to penicillin and are at low risk of an allergic response

What does the study involve?
The DOC clinic is a hospital procedure involving the consumption of a child dose of amoxicillin (25 mg) orally followed by 1 hour of direct observation. If no symptoms are noted, the participant will take a second dose of amoxicillin (250 mg) and be observed for another hour. Participants will be asked to complete a satisfaction survey before they leave. Participants will be contacted at regular intervals to ensure no delayed response (by the medical team). Participants will complete another survey at 6 and 12 months to investigate their confidence in taking penicillin.
The researchers are also asking to include general screening information collected before the oral challenge (regarding previous exposure to penicillin, reactions, family history etc). The surveys at 6 and 12 months will allow the study team to learn if participants have had to take

penicillin or another antibiotic from the penicillin family (like amoxicillin) and if they had any negative effects. Each of these surveys is about six questions long and asks for information like how well the procedures were explained, was the location convenient, did you experience a reaction, did you feel safe while at the DOC clinic, etc.

What are the possible benefits and risks of participating?
The benefit of the DOC is enabling patients to be prescribed the appropriate antibiotic when they need treatment. Antimicrobial resistance is a very serious problem and patients labelled with penicillin allergies who are not truly allergic are at risk of being treated with extreme antimicrobials and developing resistance. The ideal treatment of any infection is to use the best antimicrobial. By removing the penicillin labels of those who are not allergic, patients will receive optimal care. The benefit of participating in the feedback program is to allow the team to determine if this clinic is feasible and practical to run. If it is, there are significant opportunities for other small rural facilities to start their own similar programs, thereby improving patient care and providing optimal treatment while reserving the strongest antimicrobials for when they are truly needed. The risk of a reaction is extremely low as a result of the screening. Patients may develop a rash, at which point the DOC would be stopped and the penicillin allergy would remain stated in their medical records. Any other reactions would be treated immediately as the clinic is directly beside the emergency unit and is supervised for the entire time the patient is within the clinic. Data breaches are possible but are very unlikely and would not affect participants as their personal data is stored as per hospital policy and their research data is unidentified.

Where is the study run from?
Muskoka Algonquin Healthcare (Canada)

When is the study starting and how long is it expected to run for?
January 2022 to March 2026

Who is funding the study?
Northern Ontario Academic Medicine Association (NOAMA) (Canada)

Who is the main contact?
Lisa Allen, lisa.allen@mahc.ca

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Study information

Scientific Title
Evaluation of direct oral challenge clinic to assess penicillin allergies in a rural Ontario Setting: pilot project

Acronym
DOC Clinic Evaluation

Study objectives
This study will investigate the feasibility of conducting a direct oral challenge (DOC; using amoxicillin) in a small rural community.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/11/2022, Laurentian University Research Ethics Board (REB) (Laurentian University Research Ethics Board Chair: Sandra Hoy, 935 Ramsey Lake Road, Sudbury, ON P3E 2C6, Canada; +1 (0)705 675 1151; Shoy2@laurentian.ca), ref: 6021290

Primary study design
Observational

Study design
Prospective feasibility design

Study type(s)
Other

Health condition(s) or problem(s) studied
Participants currently labelled with a penicillin allergy who are screened as low risk

Interventions
The DOC is established within the hospital with similar screening protocols used elsewhere. The research involved in this study is to determine if this clinic is feasible for small rural centres. Using the hospital protocol, team physicians will screen volunteers for inclusion in the DOC. Participants must be confirmed to be a low risk to participate in the DOC. The research aspect of this study involves participant feedback about the DOC, its location, scheduling, and investigation about if the clinic is sustainable and effective at delabelling participants who are found not to be allergic to penicillin.

Intervention Type
Mixed

Primary outcome(s)
1. The recruitment pathway for participants to the DOC, measured by identifying all areas participants are referred from, and tabulating total interest (number of participants contacting

the DOC) and reasons for not participating (patient satisfaction survey), immediately following the DOC and continuous
2. Participant satisfaction regarding the DOC, measured using a participant feedback survey completed (ongoing) by each participant immediately after attending the DOC
3. Physician feedback regarding the DOC, both participating physicians and those PCP of patients who may attend the DOC, measured using a physician feedback survey at 12, 24 and 36 months after program initiation
4. Complications noted within the DOC measured using the data acquisition sheet, compiled quarterly and reported annually to the REB and at project completion
5. Collaborative experience of the clinic, the hospital and the research team for the DOC, measured using retrospective reporting and qualitative interviews at 24 and 36 months
6. Program feasibility in small rural centres, measured using the total number of participants, number of participants screened out, number of participants completing the DOC and the number of participants reporting confidence in being prescribed penicillin in the participant questionnaire at 6, and 12 months after the DOC (for each patient)
7. Template of the program for similar communities who may want to replicate the program, measured using processes completed and adapted (if required) at 36 months

Key secondary outcome(s)
The overall program cost/benefit for the clinic measured using cost estimation for clinic and administrative time compared to cost estimation for participants to receive skin testing at 36 months

Completion date
02/03/2026

Eligibility

Key inclusion criteria
All participants who attend the DOC are eligible to provide feedback. To participate in the DOC there are eligibility requirements to ensure participants are at low risk of an allergic response. Whether attendees complete the DOC or not they will be asked to provide feedback and satisfaction regarding the clinic.

Low risk for penicillin allergy:
1. No penicillin reaction in the past 10 years
2. Never hospitalized with a reaction to penicillin
3. No evidence of a severe cutaneous adverse reaction (SCAR)
4. No evidence of drug-related eosinophilia and systemic symptoms (DRESS)
5. No history of asthma
6. Cannot recall nature of reaction or history of isolated non-allergic symptoms (e.g., GI upset only) or pruritus only without rash or simple macular papular rash as a child with amoxicillin
7. Only a family history of reaction
8. No history of IgE-mediated hypersensitivity reaction or angioedema

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
61

Key exclusion criteria
For the data collection there are no exclusion criteria. The DOC excludes moderate and high-risk allergy participants. Additionally, any sign of a reaction within the clinic would disqualify the participant from further participation. However, the research study will request those participants' feedback.

Date of first enrolment
15/02/2023

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
Canada

Study participating centre
Muskoka Algonquin Healthcare
100 Frank Miller Drive
Huntsville
Canada
P1H1H7

Sponsor information

Organisation
Northern Ontario Academic Medicine Association

ROR
https://ror.org/01pnybk10

Funder(s)

Funder type
Other

Funder Name
Northern Ontario Academic Medicine Association

Alternative Name(s)
NOAMA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analyzed during the current study will be available upon request from Lisa Allen (lisa.allen@mahc.ca). The dataset will be available after the study is published. Data made available will be patient survey/questionnaire, and adverse events and complied data based on the attached data acquisition form. Consent is required from participants and is obtained through written informed consent. Data will only be shared in a complied form with no fewer than five data points per question. The remaining details will be provided as the study is closer to concluding.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Data Acquisition Sheet		07/02/2023	Yes	No
Other publications	Participant Feedback Survey		07/02/2023	Yes	No
Other publications	Participant Questionnaire for 6 and 12 months		07/02/2023	Yes	No
Protocol file			07/02/2023	No	No