RUTGERS HEALTH
Robert Wood Johnson Medical School

Department of Emergency Medicine

CONSENT TO TAKE PART IN RESEARCH



Title of Research: PAGE-1: 1-hour Premedication for Allergy Goal in Emergency
Principal Investigator: Chirag N. Shah, MD, Paul Peng, MD, MSCR, PhD (Co-PI)

RESEARCH SUMMARY: This consent form is part of an informed consent process for research study, and it will provide information that will help you decide whether you want to take part in this **research**. It is your choice whether to take part or not.

P**URPOSE**: To determine if there is a difference in the risk of allergic reactions among adults with a documented history of iodinated contrast before a CT (computed tomography) scan, comparing premedication times of 1 hour and 4 hours. A CT scan is an imaging test that helps healthcare providers detect diseases and injuries. It uses a series of X-rays and a computer to create detailed images of your bones and soft tissues. A CT scan is painless and noninvasive.

RISKS/BENEFITS: Participating in this study does not offer any direct benefits. However, if we find that there is no significant difference in the occurrence of allergic reactions between patients who receive pre-medication for 1 hour and those who receive it for 4 hours, implementing a 1-hour pre-medication protocol could help streamline CT procedures. This change would facilitate faster CT performance and allow for quicker initiation of treatment.

ALTERNATIVES: You may choose not to participate in this study. You may also choose to decline randomization (a common way participants are assigned to different treatment groups by chance). Since randomization is required to assign participants to treatment groups, declining randomization will make you no longer eligible to participate in this study. If you choose not to participate in the study or decline randomization, you will follow the standard 4-hour premedication regimen.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
Dr. Chirag Shah is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

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Dr. Shah may be reached at shahcn@rwjms.rutgers.edu or 732-235-8717. Dr Peng may be reached at paul.peng@rwjms.rutgers.edu or 732-633-1402. Robert Wood Johnson University Hospital New Brunswick, NJ

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this research being done?
The purpose of this research is to define no difference in allergic reactions for a 1-hour premedication time compared to the usually used 4 hours.

Who may take part in this research and who may not?
You may participate in the study if:
- you are an Adult (≥ 21 years old)
- have a documented iodinated contrast allergy in the electronic health record
- have a contrast CT scan ordered
- Willing and able to give consent

You may not participate in the study if you:
- previously enrolled in this study
- are pregnant
- have a seafood or iodine allergy
- have a Gadolinium allergy

Why have I been asked to take part in this research?
You have been asked to take part in this research because you are in the ER, have a contrast allergy, and are going to receive a CT scan in the Emergency Room (ER).

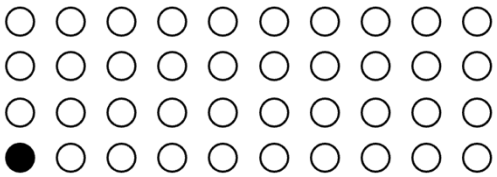
How long will the research take and how many participants will take part?
We are recruiting 213 patients in the shorter and longer groups (426 in total). You will be a part of the study until your CT scan is complete, and we have assessed for any contrast reaction after 30 minutes of the CT scan. Depending on which premedication time you are randomized to, your time in the search may be approximately 1-2 hours or 4-5 hours (not accounting for other tests in the ER). Your participation ends once we have checked for a contrast reaction. The length of time of research will last as long as the time you are in the ER.

What will I be asked to do if I take part in this research?
- You will be given an IV with the standard medications (steroid and Benadryl) normally given to someone with a contrast allergy.
- If you are in the 4-hour group, you will complete the CT scan in about 4 hours, which is the standard protocol.
- If you are in the 1-hour group, you will complete the CT scan in approximately 1 hour, as per the experimental protocol.

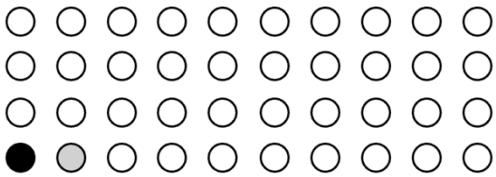
What are the risks of harm or discomforts I might experience if I take part in this research?

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About 1 in 40 patients have a contrast reaction even with 4-5 hours of premedication:



No trial has ever studied a 1-hr protocol. Our research estimates that 1-2 in 40 patients have a contrast reaction with 1-hr of premedication:



The estimated risk of a severe reaction is 4 in 10,000

Regardless of the duration of premedication or when the CT scan is performed, the emergency department team continuously monitors this risk to ensure appropriate care for patients experiencing a contrast reaction.

Are there any benefits to me if I choose to take part in this research?
Participation in this study may not yield immediate benefits for participants. However, the study findings will determine the best duration of pre-medication for patients undergoing CT contrast, ultimately helping to minimize the risk of allergic reactions.

What are my alternatives if I do not want to take part in this research?
The following alternative treatments are available if you choose not to take part in this research: You may choose not to participate in this study. You may also choose to decline randomization (a common way participants are assigned to different treatment groups by chance). Since randomization is required to assign participants to treatment groups, declining randomization will make you no longer eligible to participate in this study. If you choose not to participate in the study or decline randomization, you will follow the standard 4-hour premedication regimen.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research.

Will there be any cost to me to take part in this study?
There are no costs to you for participating in this research.

Will I be paid to take part in this study?
You will not be paid to take part in this research.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. We will be recording which group you are randomized to, as well as any contrast reaction. We will use your medical record number only to link to a study ID that is stored in a HIPAA-compliant data server. Any analysis will use the de-identified study ID

The research team may use or share your information collected or created for this research with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

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A description of this clinical trial is available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to my information—data, recordings and/or images—and bio-specimens collected for this research after the research is over?

After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I am injured during this research?

For Research on Participants with a Disease or Medical Condition:
As mentioned earlier, there is a rare chance of allergic reaction and even more rare chance of anaphylaxis. However, if you do develop a reaction, the University will make appropriate referrals for medical treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University, and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Chirag Shah (shahcn@rwjms.rutgers.edu, 732-235-8717). Emergency Department, Robert Wood Johnson University Hospital New Brunswick, NJ

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Chirag Shah (shahcn@rwjms.rutgers.edu, 732-235-8717). 1 Robert Wood Johnson Place, MEB Rm#288, Emergency Department, New Brunswick, NJ 08901

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described

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here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is the purpose of the research and how will my information be used?
You are invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research is to help investigators answer the questions that are being asked in the research.

What information about me will be used?
- Emergency Medicine clinician notes related only to the index encounter date
- All information in your medical record
- Radiology records or images (CT)
- Medical history or treatment
- Medications

Who may use, share or receive my information?
The research team may use or share your information collected or created for this research with the following people and institutions:
- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary for Clinical Care:
    - Robert Wood Johnson University Hospital (RWJUH)

Will I be able to review my research record while the research Is ongoing?
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say Yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: Chirag Shah (shahcn@rwjms.rutgers.edu).

How long will my permission last?
Your permission for the use and sharing of your health information will last until the end of the research.

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AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

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