SOL Liver & Heart (NAFLD)
MRI Screening Questionnaire (NME)
QxQ

4/7/2021

General Information

The MRI Screening Questionnaire is used to determine eligibility for the SOL Liver and Heart Study. The questionnaire is administered once the participant has been approached and received a brief description of the study, typically by telephone (Telephone Script). Much of the questionnaire can be completed initially by telephone, but certain questions require in-person assessment. The questionnaire can be administered to screen out ineligible participants by telephone. If the participant remains eligible after telephone-based questioning, the participant can next have the informed consent reviewed over the phone. If based on this preliminary informed consent, the participant remains interested, s(he) can be scheduled for a face-to-face visit after administration of the covid-19 screener determines eligibility for in-person participation.

Question by Question Instructions

Initial study eligibility

1. Check whether participant is (YES) or is not (NO) interested in MRI.

2. If answer to question 1 is NO, please indicate the reason (free text field).

MRI eligibility screening based on participant interview: *Enter initials of staff administering questions.*

3. Ask the participant if s(he) has a pacemaker, implanted cardioverter defibrillator, nerve or bone stimulator or any implanted electronic or metallic device inside his/her body. If the answer is YES, please so indicate. Examples of metallic implants include cranial plates, hip replacements, knee replacements, and surgical screws. Although some metallic implants are MRI safe, we will not be obtaining medical records or following up with participants' health providers to determine the type of implant and its safety for MRI. Unless a participant knows with confidence that their implant is MRI compatible because they have had an MRI safely after its insertion, and the field center clinician approves proceeding, the answer should be YES. If the participant is uncertain, consultation of the clinician may likewise be made at staff discretion. But if it cannot be determined with confidence that the answer is NO, an answer of YES should be recorded. If the metallic implant is removable, for instance, external piercings or rings, the answer will be a NO so long as the participant is willing and able to remove these. If these will not or cannot be removed, the answer will be YES. As with all implants, it will ultimately be the judgment of local MRI facility staff as to whether a participant's implant is

safe for MRI, and local facility MRI staff can be consulted if there is uncertainty. *A response of YES is a contraindication to MRI, and the interview can conclude.*

4. Inquire if the participant has ever had brain surgery for a cerebral aneurysm and respond if YES or NO. Such surgery is associated with presence of metallic clips in brain arteries. *A response of YES is a contraindication to MRI, and the interview can conclude.*

5. Ask the participant if s(he) is claustrophobic or feels particularly anxious in closed, confined spaces. If the participant indicates that the anxiety is at a level where s(he) would not, or probably would not, be able to remain in the MRI scanner for approximately 1 hour, mark the answer as YES. Otherwise mark the answer as NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

6. Ask participant for his/her weight. This can be confirmed by weighing the participant on a scale at the time of the initial visit at staff and field center investigators' discretion. If self-reported weight is greater than 350 lbs (greater than 159 kg), answer the question as YES, and NO otherwise. *A response of YES is a contraindication to MRI, and the interview can conclude.*

7. *For Chicago and San Diego sites only.* Ask the participant for his height. Use the link: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm to calculate body mass index (BMI) by entering participant's height and weight. Height and weight can be entered in standard units (feet and inches, lbs) or metric units (centimeters and kilograms). If BMI≥40 kg/m^2 in men or BMI≥35 kg/m^2 in women, the participant must have measurement of sagittal abdominal diameter at an initial visit before MRI is scheduled to make sure that participant's vertical dimension when supine will allow him/her to fit in the scanner. If BMI≥40 kg/m^2 in the case of a man or BMI≥35 kg/m^2 in the case of a woman, do not enter a response until the participant has undergoes measurement of sagittal abdominal diameter. Otherwise, enter a response of NO.
(Of note, we are modifying sagittal abdominal diameter here to apply to the largest vertical height of the *abdomen or chest* when lying on his/her back. If the greatest vertical dimension is not at the level of the abdomen but of the chest, then this effectively becomes the sagittal thoracic diameter.) On a measurement is made, if the highest vertical dimension of the abdomen or chest is ≥32 cm, please answer with YES. Otherwise enter a NO. *A response of YES is a contraindication to MRI.*

8. For women, inquire if the participant is pregnant. This should be asked of all women 60 or younger. If the participant is uncertain, a urine pregnancy test will be necessary. If the participant knows that she is pregnant, enter an answer of YES. Otherwise, enter NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

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9. Ask if the participant has ever been shot with bullets, BBs or shrapnel. Indicate if YES or NO. If the participant is unsure, enter a YES. *A response of YES is a contraindication to MRI, and the interview can conclude.*

10. Inquire if the participant has ever been a machinist, welder or metal worker, or if s(he) has ever had metal removed from his/her eyes. If the participant gives a positive response or is unsure, enter YES. Otherwise enter NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

11. Ask if the participant uses hearing aids or has ever had a cochlear (inner ear) implant. If the participant gives an affirmative response or is uncertain, enter YES. Otherwise enter NO. *A response of YES is a contraindication to MRI, and the interview can conclude.*

12. Determine if the participant has had heart surgery for replacement of a valve with a prosthesis. Because such prostheses can interfere with imaging of the heart, such participants will be excluded. Enter a response of YES or NO. *A response of YES excludes the participant from MRI, and the interview can conclude.*

13. Ask if participant is able to have an MRI by being inside a scanner for about 60 minutes. Enter a response of YES or NO. *A response of YES excludes the participant from MRI, and the interview can conclude.*

If any response in a gray cell is marked, the person is not eligible for study participation.

IV contrast eligibility screening based on participant interview: *Enter initials of staff administering questions.*

14. Inquire if participant has had an MRI with gadolinium contrast (injected dye used in MRI studies) in the past 6 months. Because we want to allow a 6-month interval before repeat administration of gadolinium contrast, the participant will not be eligible for MRI with contrast if gadolinium was administered within this period. Note that other kinds of contrast, such as for computed tomography (CT), are not relevant to administration of gadolinium and do not count. Answer with a YES or a NO. *If YES, the participant cannot have an MRI with contrast until the 6-month interval is met.* The preference is to recontact the participant at a later date to schedule the contrast MRI once the requisite time period has elapsed. An alternative is to enroll the participant for non-contrast MRI now if s(he) is eligible.

15. Ask if the participant has a history of allergic reaction to MRI gadolinium contrast. Again, note that gadolinium is different than the contrast administered for computed tomography (CT). A mild or moderate allergic reaction to CT contrast is not a contraindication to MRI with

contrast, but will need to be detailed in the Asthma and Allergy Screening Questionnaire. Indicate a response of YES or NO. *If YES, participant is ineligible for contrast MRI.*

16. Inquire if participant is currently receiving dialysis (hemodialysis or peritoneal dialysis) for end-stage kidney disease. Enter YES or NO. *If YES, participant is ineligible for contrast MRI.*

17. For women, ask if they are currently breast feeding. Enter YES or NO. *If YES, participant is ineligible for contrast MRI.*

If any response in a gray cell is marked, the person is not eligible for IV contrast.

If participant eligible for IV contrast, proceed to Asthma and Allergy screening.

18. Ask if participant has a history of asthma. If YES, proceed to Asthma and Allergy Screening Questionnaire. Otherwise enter a response of NO. If there is a history of asthma, indicate after completing Asthma questionnaire if contrast is contraindicated by entering a response of YES. If there is no history of asthma, or if Asthma questionnaire indicates that participant is eligible for contrast, enter a response of NO. *If YES is marked, participant is ineligible for contrast MRI.*

19. Ask if participant has a history of allergies to food, drugs or insect stings. If YES, proceed to Asthma and Allergy Screening Questionnaire. Otherwise enter a response of NO. If there is a history of such allergies, indicate after completing Allergy questionnaire if contrast is contraindicated by entering a response of YES. If there is no history of allergies, or if Allergy questionnaire indicates that participant is eligible for contrast, enter a response of NO. *If YES is marked, participant is ineligible for contrast MRI.*

20. If participant is eligible for MRI (with or without contrast) based on responses to questions 3 through 17 and 18 through 19, proceed with obtaining preliminary phone consent. Once written informed consent is given, enter a response of YES. If written informed consent is declined by participant, enter NO. If only preliminary consent has been obtained over the phone, leave blank. If YES, proceed to in-person laboratory testing.

MRI or IV contrast eligibility based on laboratory testing: *To be completed after participant consented. Enter staff initials.*

21. Enter value of estimated glomerular filtration rate (eGFR) based on creatinine testing from either point-of-care StatSensor test or Core Laboratory testing. The eGFR is determined by using the Modification of Diet in Renal Disease (MDRD) calculator provided in the following link: https://www.mdcalc.com/mdrd-gfr-equation. Enter participant sex, age and creatinine value. Record the lower value of the eGFR range reported by the calculator. If it is <45 ml/min/1.73

m^2, enter a response of YES. Otherwise enter a response of NO. *If YES is marked, participant is ineligible for contrast MRI.*

22. For women age 55 or younger, ask the date of the last menstrual period and enter it on the form. If this is 12 months or longer from the date of questioning, the participant can be considered post-menopausal. Also, ask these female participants age 55 or younger if they have had prior surgery to remove the uterus and/or both ovaries. Removal of the uterus or both ovaries would make them incapable of conceiving a child. Field centers and staff will use their discretion on whom to do a urine pregnancy test on. But field centers may consider giving a urine pregnancy test to all women age 55 or younger. It is encouraged that this be done at the time of the initial visit, but irrespective of whether it is performed at this visit, urine pregnancy testing should be conducted in all women of childbearing potential on the day of MRI prior to being cleared to have the scan. For this question, enter a response of YES if the participant is a woman of childbearing potential, and NO otherwise. *If YES, this person must undergo urine pregnancy testing before having MRI.*

23. If the answer to question 22 is YES, indicate if urine pregnancy test is positive by entering a response of YES. If the urine pregnancy test is negative, enter a reponse of NO. If urine pregnancy test is not performed at this time or is not necessary, leave blank.

24. Indicate if participant is eligible for MRI based on the interview and any laboratory testing performed as of the date of form completion. For participant to be eligible, s(he) must have no shaded boxes for relevant answers. If later testing, namely, a subsequently positive urine pregnancy test, makes the participant ineligible for MRI subsequently, this can be entered on the same form template in cDART at a later date. Enter a response of YES or NO as appropriate. *If NO, participant is ineligible to take part in MRI.*

25. Indicate if participant is eligible for IV contrast MRI based on interview and any laboratory testing performed as of the date of form completion. For participant to be eligible, s(he) must have no shaded boxes for relevant answers. If later testing, namely, a subsequently eGFR<45 ml/min/1.73 m^2, makes the participant ineligible for IV contrast subsequently, this can be entered on the same form template in cDART at a later date. Enter a response of YES or NO as appropriate. In the presence of an asthma or general allergy history, if the Asthma and Allergy Screening Questionnaire initially showed that the participant is eligible for contrast, but there is no health care professional on site to reassess the participant, enter NO. *If NO, participant is ineligible to have a contrast MRI.*

26. Enter initials of staff reviewing consent, form questions 3-17, Asthma and Allergy Screening form and laboratory test results, and determining that participant consented to and is eligible for MRI and/or IV contrast.

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If participant is consented (preliminarily or fully), that is question 20 is a YES or blank, and is eligible (question 24 is a YES), the participant may be scheduled for MRI. An MRI with contrast may only be scheduled if the answer to question 25 is a YES. Note that if only a preliminary consent has been obtained and a creatinine value has not been measured (no calculated eGFR), these will need to be done on the day of the in-person visit for MRI prior to being eligible to undergo the procedure or receive contrast.

If the participant is eligible, proceed to administration of informed consent, to be completed in person at the time of the initial visit. Prior to scheduling the initial visit, the MRI Screening Questionnaire is and after the Covid-19 Screener responses indicate that the participant is eligible to come in for an in-person visit.