

Guidelines for MRI and PET Scanning Women of Childbearing Age

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MR and PET scanning of women of childbearing age (i.e. pre-menopausal) brings with it special considerations that researchers must be aware of before they come to scan at Monash Biomedical Imaging. As MBI is a research facility, we apply more stringent exclusion criteria than those used in clinical situations in order for this group to be deemed safe to undergo these procedures.

MRI Scanning

Women in the first trimester of pregnancy **should not** have an MRI scan for research purposes. The MBI “3T MRI Safety screening and information form” includes the questions:

“Are you pregnant, suspect you may be pregnant or breastfeeding? NO / YES”

A “No” answer is deemed enough to satisfy our legal requirements regarding safety of the procedure. If the participant answers “YES” to possibly being pregnant and/or is in the first trimester the scan **MUST NOT** be performed.

Women in the second and third trimester are discouraged from having an MRI scan for research purposes. An exception is if the study is on pregnant women and all the appropriate Monash University Human Ethics approval has been obtained.

If participants answer “YES” to breast-feeding the MRI can still be done as no contrast is given at MBI.

MR-PET Scanning

Adding simultaneous PET scanning to an MRI brings with it much more stringent selection requirements. To ensure we meet our legal obligations, and to maintain our radiation licence, MBI must have procedures in place to ensure that pregnant women are not injected with radiopharmaceuticals and scanned.

The NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015) says that:

“4.1.1 The wellbeing and care of the woman who is pregnant and of her fetus always takes precedence over research considerations.

4.1.10 It is ethically unacceptable to conduct non-therapeutic research that involves administering drugs or carrying out a procedure on the woman or her fetus, where the research carries risk for the fetus.”

ARPANSA’s code of practice on “Exposure of Humans to Ionizing Radiation for Research Purposes” also states “where pregnancy status is uncertain...premenopausal women should have a biochemical pregnancy test to exclude pregnancy before radiation exposure.”

Therefore researchers should have a clear and frank conversation with their participants about whether they could possibly be pregnant. Urine strip pregnancy tests are not considered sensitive enough to prove non-pregnancy. Only a beta hCG blood test performed before the scan can be accepted as positive proof of non-pregnancy when there is any uncertainty.

The procedure, therefore, to be adopted at MBI and to be followed by the researchers is as follows:

- 1) The participant is given the appropriate MBI “MRI-PET Screening and Information form” by the researcher at least 24 - 48 hours before attending for the scan. The following section relevant to pregnancy/breast feeding is included on the form:

“PET SAFETY SCREENING INFORMATION

MEDICAL HISTORY:

PET procedures involve the injection of small doses of radioactive pharmaceuticals. The risks of these procedures are very small and are similar to having other radiology procedures like a CT scan. However, the effect on an unborn child is not fully understood. Therefore, it is best not to perform these procedures in pregnant women.

Please think carefully about whether you may be pregnant.

Are you pregnant, suspect you may be pregnant or breastfeeding?.....NO / YES”

If they answer yes to possibly being pregnant then it is the researcher’s decision as to whether to disqualify the participant or to obtain a beta hCG blood test before attending MBI.

If they answer “YES” that they are breastfeeding then the ARPANSA code of practice states “In the case of studies involving the administration of radioactive substances, research participants who are breast feeding must be excluded unless conditions specific to this group are being investigated.”

- 2) On the day of the scan the nuclear medicine technologist and the radiographer will discuss the screening form with the participant. If they answer “NO” to the statement

“Are you pregnant, suspect you may be pregnant or breastfeeding?.....NO / YES”

they will be deemed to be safe to proceed with the MR-PET scan, provided there are no other contraindications for the scan.

- 3) If the participant indicates that there is any chance they may be pregnant, and a negative beta hCG test result is not available, the scan MUST NOT proceed.

If the participant indicates they are breast-feeding the scan will not be performed unless the research group is breast-feeding women and all appropriate Monash University Human Ethics approval has been obtained.

Note that if the scan does not proceed, the researcher will still incur the costs associated with the scan, including booked scanning time and the costs for radiopharmaceutical supply.

The MBI radiographers and nuclear medicine technologists are available to assist researchers with any queries regarding safety and acceptability criteria for participants in MRI or MR-PET research projects at MBI. Researchers are encouraged to make full use of their knowledge and experience.