



SOL Liver & Heart (NAFLD) Biospecimen Collection - Bilingual (NBB) QxQ

5/17/2021

General Instructions

Participants in the SOL Liver & Heart (NAFLD) study will have a single EDTA tube blood collected. The NBB - Biospecimen Collection form is completed during the participant's visit to record information on the collection of the blood sample. Technicians performing venipuncture must be certified and should have a working knowledge of the SOL Liver and Heart (NAFLD) Biospecimen Collection and Processing Manual.

The blood collection may take place during the regular V3 blood collection at the clinic site, at a separate time at the clinic site, or at the MRI Center. Each location must follow the same protocols. One exception is that blood collections done at the MRI Center may involve blood collection from an IV line. If the SOL Liver Heart Study blood is collected at the same time as the regular V3 blood collection, the blood tube for the ancillary study should be collected last, after all the tubes have been collected for the core study, including any phantom ID QC collections. If the SOL Liver Heart Study blood is not collected during the V3 core visit, it should be collected preferably within one month of this visit, although up to 12 months delay is acceptable.

Blood Minimum Volumes

1. If the SOL Liver Heart blood sample is collected during the V3 core visit, a minimum collection volume of 5 mL is required. If the minimum volume is not obtained, the sample should not be sent to the central laboratory. The sample and Biospecimen Collection Form should be discarded and the blood collection should be attempted at another visit; another visit can be scheduled at the clinic site, or blood collection can be attempted at the MRI visit.
2. If the SOL Liver Heart blood sample is collected during the MRI visit, there is no minimum volume required. Any sample obtained should be sent to the central laboratory.

Place bar code Lab ID# labels in the appropriate spot at the top of the form that matches the collection tube being used for a participant's specimen. The correct pairing of the specimen ID# with the HCHS/SOL ID# is *critical* for routine results reporting and safety monitoring of clinical laboratory measurements.

QxQ Instructions

Note: Use the language preferred by the participant when asking all five of the safety screening questions.

A. Sample Collection Questions

A1. Safety Questions



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1. If the participant has had a radical mastectomy or other surgery where lymph nodes were removed from their armpits, Notelogs which arm, specify the issue in Q12, and do not perform venipuncture on that arm. **If lymph nodes were removed from both armpits, venipuncture cannot be performed on this participant.**

If needed, English and Spanish information sheets from the Susan G. Komen foundation are found at the end of this document, and describe different types of mastectomies to assist participants in indicating the correct procedure they may have had.

2. If participant has a bleeding disorder, Notelogs the type, specify in Q12, and consult with the field center physician, physician assistant, or nurse practitioner before proceeding with the venipuncture. If the participant does not know whether he/she has a bleeding disorder, offer the explanation: "If you have a bleeding disorder you would have symptoms like excessive nose bleeds, or very easy bruising, or problems with bleeding after tooth extractions, or any type of surgery." If the participant is still unsure, consult with field center medical personnel before continuing.
3. If a participant has a graft or shunt for kidney dialysis, Notelogs which arm, specify in Q12 and do not perform venipuncture from the arm with the graft or shunt. **If the participant has a graft or shunt in both arms, venipuncture cannot be performed on this participant.**

A2. Fasting Blood Collection Information

4. Select the answer that best indicates the last day the participant ate or drank anything (other than water).
5. Enter the time that the participant ate or drank anything (other than water).

A3. Blood Collection

6. Enter the date of the blood collection.
7. Enter the time of the blood collection using 24-hour format (i.e. 13:00 = 1:00pm).
8. Enter the number of venipuncture attempts. Include all venipuncture attempts by all phlebotomists. The same technician should not attempt a venipuncture more than twice.
9. Indicate if the blood sample was obtained via an IV at the MRI center following the protocol outlined in Appendix 5 of the NAFLD MOP.



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10. Indicate if there were any problems with the blood collection. If Yes, specify in Q11 and/or in Q12.
11. a-f. If any of the listed blood drawing incidents or problems occurred, indicate by selecting Yes or No for each item. If a specific incident or problem is not listed, document it on Q12. If there were no incidents or problems, skip to Q13.
12. Enter any comments, incidents or blood drawing problems that were not listed in Q11, and include items identified in the safety questions.
13. Enter the ID code for the technician who collected the blood. If more than one technician attempted to draw the blood, enter the code of the first technician.

References - Breast surgery/mastectomy information sheets:



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DATOS PARA LA VIDA Cirugía de cáncer de seno

El propósito de la cirugía de cáncer de seno es extraer el tumor completo del seno. Algunos de los ganglios linfáticos del área de la axila (ganglios linfáticos axilares) posiblemente también se extirpen para ver si hay células cancerosas.

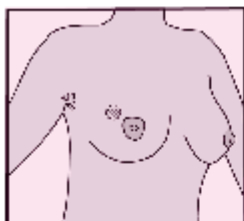
Además de la cirugía, el tratamiento también puede incluir radioterapia, quimioterapia, terapia hormonal y/o terapia dirigida. Estos tratamientos ayudan a destruir células cancerosas que puedan quedar en el cuerpo.

Tipos de cirugía de cáncer de seno

Hay dos tipos de cirugía de cáncer de seno: lumpectomía (cirugía de conservación de seno) y mastectomía. La supervivencia bajo el tratamiento de lumpectomía más radioterapia es la misma que con la mastectomía.

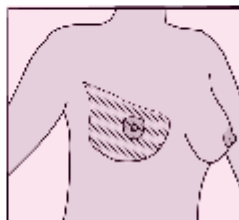
Lumpectomía (casi siempre va seguida de la radioterapia):

En la lumpectomía, el cirujano extrae el tumor y un pequeño borde del tejido normal alrededor de éste. El resto del seno permanece intacto. La lumpectomía casi siempre va seguida de la radioterapia.



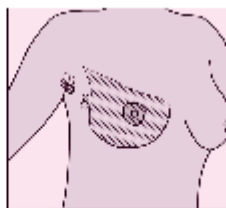
Mastectomía

En la mastectomía se quita todo el seno por completo. En algunos casos, la radioterapia puede suministrarse después de la mastectomía.



Mastectomía total:

El cirujano extrae todo el seno y el recubrimiento de los músculos del tórax, pero ningún otro tejido.



Mastectomía radical modificada:

El cirujano extrae el seno por completo, el recubrimiento de los músculos del tórax y algunos ganglios linfáticos axilares.

Mastectomía de salvamento de la piel y mastectomía de salvamento del pezón

Si le van a hacer cirugía de reconstrucción al mismo tiempo que mastectomía, es posible que el cirujano aplique una técnica de salvamento de la piel o técnica de salvamento del pezón.

Una mastectomía de salvamento de la piel preserva tanta parte de la piel como sea posible. El cirujano plástico puede usar esa piel para ayudar a formar el seno reconstruido. Una mastectomía de salvamento del pezón es una mastectomía de salvamento de la piel que también conserva intacto el pezón y la areola (el círculo de piel sombreada alrededor del pezón).

Para obtener más información, visite komen.org o bien, llame a la línea de Susan G. Komen para el cuidado de los senos al 1-877-465-6636 (1-877 GO KOMEN) de lunes a viernes, de 9 a.m. a 10 p.m., hora del Este.

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SUSAN G. KOMEN.

BREAST CANCER SURGERY

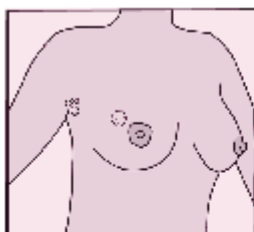
The goal of breast cancer surgery is to remove the entire tumor from the breast. Some lymph nodes from the underarm area (axillary lymph nodes) may also be removed to check for cancer cells.

Besides surgery, treatment may also include radiation therapy, chemotherapy, hormone therapy and/or targeted therapy. These treatments help kill any cancer that might still be in the body.

Types of breast cancer surgery

There are 2 types of breast cancer surgery: lumpectomy (breast conserving surgery) and mastectomy. Survival with lumpectomy plus radiation therapy is the same as with mastectomy.

Lumpectomy:



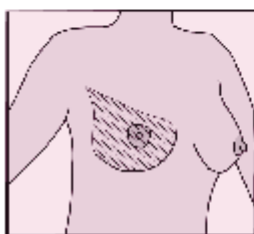
With a lumpectomy, the surgeon removes the tumor and a small amount of normal tissue around it. The rest of the breast remains intact. Most often, the general shape of the breast and nipple area are retained.

A lumpectomy is also sometimes called breast conserving surgery, partial mastectomy or wide excision.

Radiation therapy is usually given after a lumpectomy to get rid of any cancer cells that might be left in or around the breast.

Mastectomy:

With a mastectomy, the whole breast is removed. In some cases, radiation therapy may be given after mastectomy.



Total (simple) mastectomy:

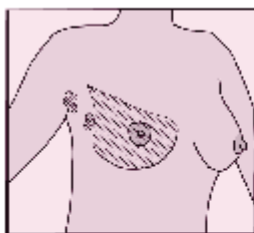
The surgeon removes the whole breast and the lining of the chest muscle, but no other tissue.

Skin-sparing mastectomy and nipple-sparing mastectomy

If you are having breast reconstruction at the same time as a mastectomy, the surgeon may be able to use a skin-sparing or a nipple-sparing technique.

A skin-sparing mastectomy saves as much of the skin of the breast as possible. The plastic surgeon can use this skin to help form the reconstructed breast. A nipple-sparing mastectomy is a skin-sparing mastectomy that also keeps the nipple and areola (the darkly shaded circle of skin around the nipple) intact.

Also, the choice of surgery does not affect whether you will need chemotherapy, hormone therapy and/or targeted therapy. Drug therapies are given based on the characteristics of the tumor, not the type of surgery you have.



Modified radical mastectomy:

The surgeon removes the whole breast, the lining of the chest muscle and some of the axillary lymph nodes.

For more information, visit komen.org or call Susan G. Komen's breast care helpline at 1-877 GO KOMEN (1-877-465-6636) Monday through Friday, 9 AM to 10 PM ET.

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