protocol for cyberknife®
treatment of accelerated partial breast irradiation

PROTOCOL | **PARTIAL BREAST IRRADIATION**

CyberKnife® Stereotactic Accelerated Partial Breast Irradiation (CK-SAPBI) Registry

ILLINOIS CYBERKNIFE®
AT ADVOCATE LUTHERAN GENERAL HOSPITAL

CyberKnife delivers targeted, concentrated beams of radiation.

CK-SAPBI Registry Summary

Illinois CyberKnife in cooperation with the department of Radiation Medicine at Georgetown University Hospital through an observational registry trial will evaluate the efficacy and toxicity of Stereotactic Accelerated Partial Breast Irradiation (SAPBI) delivered with the CyberKnife in early stage breast cancer. We will evaluate oncologic and cosmetic outcomes. CyberKnife Radiosurgery is defined as the stereotactic delivery of ionizing radiation in 5 or less sessions over 5 to 10 days to a designated target with sub-millimeter accuracy. Radiosurgery in the context of this registry will be given to the region of the tumor bed within 12 weeks of breast conserving surgery. This study will accrue 200 subjects over a two year period.

Clinical Background

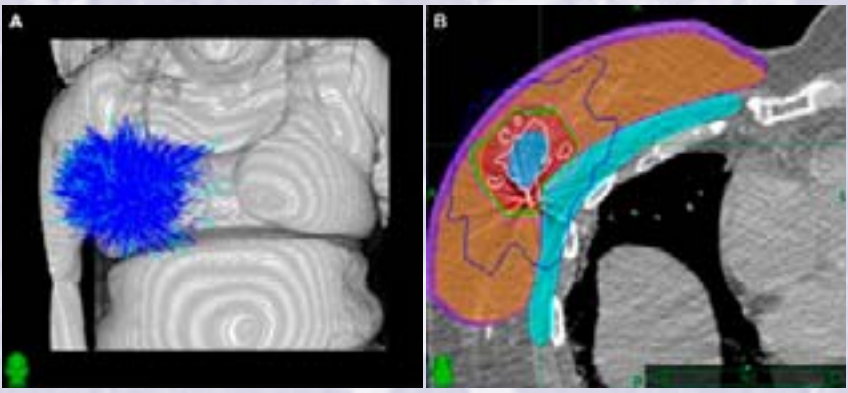
Breast conserving therapy is the preferred treatment approach for early stage breast cancer.[1] Numerous randomized controlled studies have demonstrated equivalent overall survival for patients receiving breast conserving surgery with whole breast radiotherapy (WBI) compared with patients treated by mastectomy alone.[2-8]. WBI disadvantage is the prolonged daily radiation duration (~6 weeks), which may pose a prohibitive burden to patients. There is a large body of mature Phase I/II and preliminary Phase III data available exploring the replacement of WBI with accelerated partial breast irradiation. There are unique advantages to using the CyberKnife radiosurgery system for partial breast irradiation. The target tracking and respiratory motion management capabilities called "Synchrony", results in smaller normal breast volumes receiving high dose irradiation while reducing radiation exposure to surrounding tissues.

Patient Eligibility Criteria:

- Breast Cancer Stage 0 or I
- Over 50 years of age
- ER+, PR+, Her2-
- DCIS or Invasive non-lobular carcinoma
- Must be within 12 weeks of lumpectomy

CyberKnife Treatment Planning:

- All patients should undergo margin negative resection with breast conserving surgery.
- Four gold fiducial markers will be placed in a manner that defines the superior, inferior, medial and lateral boundaries of the lumpectomy cavity and allows for optimal Synchrony motion tracking.
- A contrast enhanced treatment planning CT scan at or above the thyroid and extend several cm below the infra-mammary fold to include the entire lung
- CyberKnife Dose Prescription - The total dose is 30.0 Gy, which will be delivered in five equal fractions of 6.0 Gy per day over 5-10 total days.



Vermeulen S, Cotrutz C, Morris A, Meier R, Buchanan C, Dawson P and Porter B (2011) Accelerated partial breast irradiation: using the CyberKnife as the radiation delivery platform in the treatment of early breast cancer. Front. Oncol. 1:43. doi: 10.3389/fonc.2011.00043

Patient Assessment:

- Clinical examination and disease status assessment will be completed at 4-6 weeks, 6 months, 12 months, 18 months, 24 months and yearly intervals thereafter for five years.

1. Treatment of Early-Stage Breast Cancer: NIH consensus statement. 1990 June 18-21;8(6):1-19.
2. Fisher B, Anderson S, Bryant J, Margolese R, Deutsch M, Fisher E, Jeong J-H, Wolmark N. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *New England Journal of Medicine 2002;* 347:1233-1241.
3. Jacobson, JA, Danforth DN, Cowan KH, D'Angelo T, Steinbert SM, Pierce L, Lippman ME, Lichter AS, Glatstein E, Okunieff P. Ten-year results of a comparison of conservation with mastectomy in the treatment of stage I and II breast cancer. *New England Journal of Medicine 1995;*332:907-911.
4. van Dongen JA, Voogd AC, Fentiman IS, Legrand C, Sylvester RJ, Tong D, van der Schueren E, Helle PA, van Zijl K, Bartelink H. Long-term results of a randomized trial comparing breastconserving therapy with mastectomy: European Organization for Research and Treatment of Cancer 10801 trial. *Journal of the National Cancer Institute 2000;*19:1143-1150.
5. Blichert-Toft M, Rose C, Andersen JA, Overgaard M, Axelsson CK, Andersen KW, Mourisden HT, et al. Danish randomized trial comparing breast conservation therapy with mastectomy: six years of life-table analysis. *Journal of the National Cancer Institute Monographs 1992;*11:19-25.
6. Veronesi U, Cascinelli N, Mariani L, Greco M, Saccozzi R, Luini A, et al. Twenty-five year follow-up of a randomized study comparing breast-conserving surgery with radical mastectomy for early breast cancer. *New England Journal of Medicine 2002;* 347:1227-1232.
7. Sarrazin D, Le M, Arriagada R, et al, Ten year results of a randomized trial comparing a conservative treatment to mastectomy in early breast cancer. *Radiotherapy and Oncology 1989;*14:177-184
8. Early Breast Cancer Trialists' Collaborative Group. Effects of radiotherapy and surgery in early breast cander: an overview of the randomized trials. *New England Journal of Medicine* 1995;333:1444-1455.

Please contact us to determine registry eligibility and referrals at (847) 723-0100.

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