<table>
<thead>
<tr>
<th>Study</th>
<th>Prospective Study of Proton Beam Craniospinal Radiotherapy in Children with Newly-Diagnosed Medulloblastoma - Assessment of Acute and Long Term Sequelae and quality of life</th>
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<tr>
<td><strong>Principle Investigator</strong></td>
<td>Joo Young Kim, M.D.</td>
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</tbody>
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| **Contact** | Joo Young Kim, M.D.  
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  +82-31-920-1724 |
| **Additional Info** | Institution  
  National Cancer Center Korea |
| **Recruitment Status** | Study Start Date: March 15, 2005  
  Estimated Primary Completion Date: April 7, 2015  
  Estimated Study Completion Date: December 2016  
  Estimated Enrollment: Ongoing, but not recruiting |
| **Study Purpose** | PURPOSE: This phase II trial is studying how well proton beam radiation therapy works in treating young patients who have undergone biopsy or surgery for medulloblastoma or pineoblastoma. |
| **Primary Aims** | 1. To assess the acute and late sequalae and the quality of life of the children treated by proton beam treatment |
| **Secondary Aims** | To determine the tumor control probability of the children treated proton beam therapy compared with the historical control rates.  
  To evaluate the radiation (and chemotherapy) induced neurocognitive and endocrine function in a systematic way.  
  To improve compliance with long-term quality of life and functional status data submission. |
| **Methods** | normalization point/dose prescription : 23.4 - 36 Gy equivalent dose (GyE)/13-20F to the target volume using 1.8 GyE equivalent fractional dose according to the risk of the patients  
  AR (Average-risk) : 32 GyE/16F boost to the primary site, 23.4 GyE CSRT --> primary site 55.4 GyE/29F/6wks  
  HR(High-risk): 20 GyE/10F boost to the primary site, 36 GyE CSRT --> 56 GyE/30F/6wks  
  M1 : 36 GyE CSRT  
  M2-3 : 36GyE for the children age<5, 39GyE for children≥5  
  Boost to the metastatic site up to 46.8 GyE ~ 54 GyE can be given depending on the age and the disease sites |
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| **Eligibility** | Patients in \(3 < \text{Age} \leq 18\) with M0–M3 treated under the KSPNO-M051/M052 scheme  
\(1 \leq \text{Age} \leq 3\) with M1–3 with planned radiotherapy after PBSCT or patients with less than 50% response to pre-PBSCT chemotherapy  
Any age with relapsed disease in the craniospinal axis who was not irradiated in the initial treatment- For these group of patients, the proton beam treatment described here is either used as a treatment guideline, or as a component of KSPNO-53  
Other primitive neuroectodermal tumors (PNET) and atypical teratoid rhabdoid tumors (ATRT)  
Histologic Confirmation for medulloblastoma; written informed consent |
| **Exclusion Criteria** | Patients who were irradiated to the tolerance dose of the neural tissues of the involved site  
Patients who are pregnant or breast-feeding will not be eligible. |