Immunotherapy (IT) with ch14.18/CHO for high-risk neuroblastoma: First results from the randomised HR-NBL1/SIOPEN trial

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for the SIOP Europe Neuroblastoma Group

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**HR-NBL1/SIOPEN**

**Eligibility**

- Definition of high-risk Neuroblastoma:
  - Stage IV: any size, any age
  - Stage IV-S: any size, any age
  - Stage IV-S with limited disease: ≤30% of bone marrow
  - Stage IV-S with extensive disease: >30% of bone marrow

**Randomised Trial Design**

- R0: Immunotherapy (IT) with ch14.18/CHO
- R3 new: Standard-of-care treatment

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**Randomisation Eligibility and Objectives**

- Randomization of standard treatment components
  - IT question: 2009-2013
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**Patients Characteristics**

- R0 Immunotherapy question: 2009-2013

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**Patients Feasibility**

- R3 Early results: Toxicity Grade 3 & 4 OoS

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**Early R2 Global Results on Primary Endpoint DFS include CR and CRp patients prior to R2 inclusion

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**Summary of R0 & R1 Results**

- GO-S: during induction significantly reduces toxicity

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**Treatment Schedule of Immunotherapy R2 ch14.18/CHO**

- R2 Early results: Toxicity Grade 3 & 4 OoS

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**Early R2 Results by Response prior to Immunotherapy

- R2 Early results: Toxicity Grade 3 & 4 OoS

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**Hypothesis: If there was manageable toxicity?**

- A view on patients having completed all IT cycles

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**New SIOPEN Immunotherapy Randomisation**

- Patients: Stage IV, Stage IV-S (unresectable or metastatic).
- Treatment: Standard of care chemotherapy followed by IT as consolidation in R0, standard-of-care chemotherapy in R3.