

**Title:** UARK 2008-01, TOTAL THERAPY 4 – A PHASE III TRIAL FOR LOW RISK MYELOMA: A RANDOMIZED TRIAL COMPARING STANDARD TOTAL THERAPY 3 (S-TT3) WITH TT3-LITE (L-TT3)

**Sponsor:** UAMS/MIRT

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**Phase:** III

**Purpose:** This study has the following specific goals:

- To find out if giving fewer courses of chemotherapy during induction (the standard first phase of Myeloma treatment) and consolidation (a combination of drugs) phases will result in fewer side effects, without reducing the overall effectiveness of treating myeloma
- To find out if changing the way the drugs are given during the transplant phase will also result in fewer side effects, while still being effective
- To find out what the effects (good and bad) of this treatment will be
- To learn more about the biology and genetics of multiple myeloma by performing imaging tests and collecting blood, bone marrow aspirate and biopsies, and biopsies of lesions seen on MRI or PET scans for research.

With this study, researchers want to find out if it will be possible to reduce some of the therapy and the way the drugs are given in an effort to reduce side effects, while still maintaining the superior results achieved with previous Total Therapy studies.

**Eligibility:** You are being asked to take part in this research study because you have active multiple myeloma that requires treatment. Up to 350 research participants, male or female, age 18 and older, regardless of race or ethnicity, will take part in this study.

**Treatment:** Participants on the L-TT3 treatment will receive one course of chemotherapy during induction and consolidation phases, while participants on S-TT3 will receive two courses in each phase. In addition, participants on L-TT3 will receive a new combination (experimental) of drugs during transplant (the drug melphalan in four small doses over 4 days in combination with 3 other drugs (bortezomib, thalidomide, dexamethasone), while participants on S-TT3 will receive melphalan the standard way during transplant (one large dose).

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