Helixor®

Mistletoe therapy for tumor patients

Influence of Helixor® A on the pharmacokinetics, pharmacodynamics and safety of gemcitabine hydrochloride (Gemzar®)

Mansky, P.J. et al.: Onkologie 31: 200S, 2008;
J ClinOncol 28: 15S, 2010

ASCO
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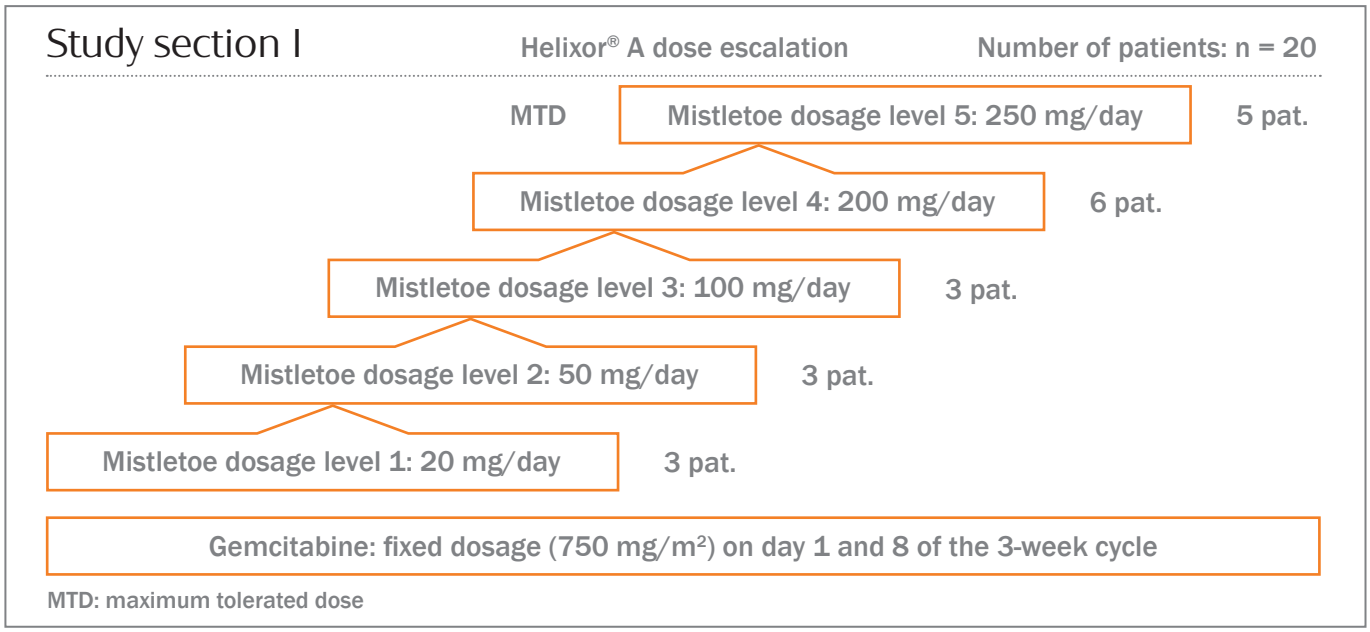
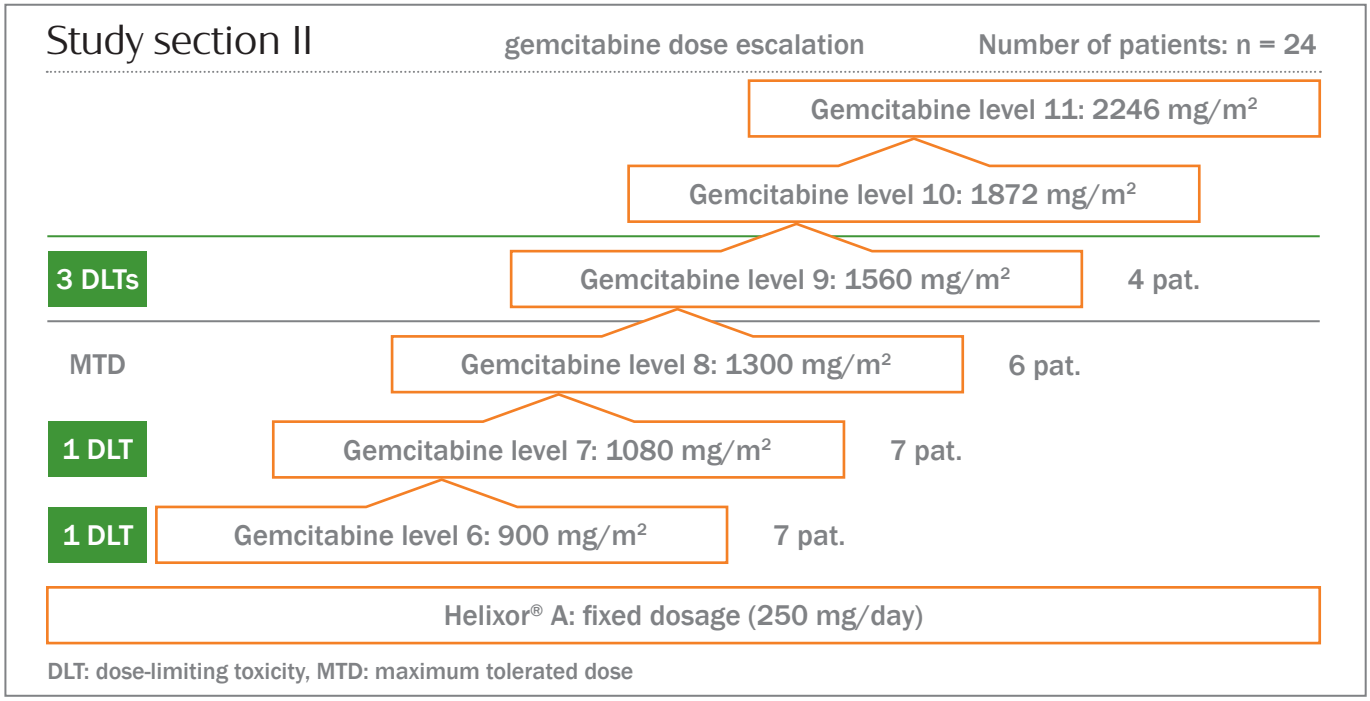
10th Annual Meeting 2010

Helixor
Bringing Life to Life.

Enabling higher dosages of gemcitabine during chemotherapy for cancer patients by using Helixor® A adjuvant therapy, with very good tolerance of the mistletoe therapy at the same time





Study section I
Testing the tolerance of Helixor® A (five-step dose escalation study) in combination with gemcitabine: **no** dosage-limiting toxicity, even with application of the highest dosage.
► Use of **250 mg Helixor® A/day** as a fixed end point for **all patients** in study section II.

Study section II
Ascertaining the maximum tolerated dosage of gemcitabine under Helixor® A adjuvant therapy with a fixed maximum dosage: discontinuation of the gemcitabine dose escalation at 1560 mg/m² (here: dosage-limiting toxicity in 75% of the patients).
► MTD of gemcitabine in combination with Helixor® A = **1300 mg/m²**

Results

- No influence of Helixor® A on the pharmacokinetics of gemcitabine
- Helixor® A: Good tolerance with excellent compliance MTD 250 mg/d; no dosage-limiting toxicity (DLT) in study section I, 1 DLT in study section II, level 9: Grade 3 cellulitis.

  Otherwise, only minor adverse effects: local reaction, fever, flu-like symptoms
- Gemcitabine: MTD 1,300 mg/m², DLT 1,560 mg/m²
  ► Problem-free dosage increase with Helixor® A from 750 to 1,300 mg/m² possible (30% higher dosage than with monotherapy)

Further results

- Significant anti-tumoral activity with the combination of gemcitabine/Helixor® A:
  6% partial remission
  42% stable disease
- Significant increase in neutrophils in study section I
- Plasma cytokine concentrations (TNFα, IL-12, IL-6, IFNγ) stable throughout
- All patients developed anti-mistletoe lectin antibodies

The last three points indicate an acquired immunocompetence despite chemotherapy.

Conclusions

Helixor® A makes chemotherapy more tolerable. The 30% higher dosage of the cytostatic drug that this enables also leads us to expect a high level of efficacy.

Indication:	Very advanced solid tumors (stage IV) (pancreatic cancer, colorectal cancer, non-small-cell lung cancer, breast cancer)
Aim of the study:	influence of Helixor® A on the pharmacokinetics, pharmacodynamics and safety of gemcitabine hydrochloride (Gemzar®)
Study design:	2-part, monocentric phase I dose escalation study
Number of patients:	44 patients (21 f, 23 m, 29-81 years)
Previous tumor treatment:	no pre-treatment (n=11), chemotherapy and/or radiation therapy (n=33)
Organization:	NCCAM/NCI
Trial center:	National Naval Medical Center, Bethesda, Maryland

Helixor®

Mistletoe therapy for
tumor patients

Integrative oncology with Helixor®

Treating tumor patients integratively

In integrative oncology, the holistic mistletoe therapy from Helixor significantly improves the quality of life for patients at all stages of tumor treatment.

It stimulates self-healing and minimizes ailments, and its efficacy has been documented in numerous reviews and trials.

Helixor
Bringing Life to Life.

For questions on eligibility for reimbursement and for medical advice:

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*free from German landlines

Helixor® A/-M/-P injection solution. Composition: Aqueous extract of fresh mistletoe leaves (1:20), special blend of winter and summer harvests in a standardized manufacturing process. Manufacturing of Helixor® A from fir mistletoe, Helixor® M from apple tree mistletoe, Helixor® P from pine tree mistletoe. The amount of fresh plant used to produce an ampoule is given in mg. **Therapeutic indications:** In accordance with the anthroposophic knowledge of man and nature. Malignant and benign tumorous diseases, stimulation of bone marrow activity, relapse prevention after tumor surgery, defined precancerous conditions.**Contraindications:** Acute inflammatory, feverish disorders, mistletoe allergy; pregnancy: if strictly indicated. **Adverse effects:** Local inflammatory reactions at the subcutaneous injection site, fever, flu-like symptoms, regional lymph node swelling, activation of inflammation, allergic reactions. **Note:** If there is a proneness to phlebitis, the injections are to be administered outside of the regions at risk of inflammation. In the event of pronounced hyperthyroidism, a delayed dosage increase is indicated. **Dosage:** s.c. according to the guidelines for treatment with Helixor®. In principle, begin with small doses. Increase dosage gradually while taking into account the patient's reaction. **Commercial forms:** Series packs (SE I - IV) with 7 ampoules; original packs (OP 0.01 - 100 mg) with 8 ampoules. Large packs and bundle packs (BP) with 4 x 7 amp. of SE II + SE IV also available.

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