











Safety and Efficacy of Mistletoe extract (Viscum album) Iscador® P in Equine Sarcoid

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Background

Equine Sarcoid (ES), a semi malignant skin tumour, is the most common neoplasia of horses (Marti et al.1993). There is no generally effective single treatment existing and the recurrence rate is high (Martens et al.2001). Furthermore as a treatment obstacle, Sarcoids tend to occur as multi-focal tumours or can be found in critical locations (peri-ocular) where success of surgical interventions is very limited (Carstanjen et al.1997). Due to encouraging results in human medicine and small animals practice after adjuvant cancer treatment by mistletoe extracts (Biegel et al. 2007) the viscum therapy could hypothetically fill a therapy gap for equine tumour diseases as well. Hence, goal of this clinical trial was to evaluate the safety and efficacy of Viscum album pini (Iscador® P) as a primary therapy of Equine Sarcoid in the context of a prospective, randomized, controlled, double-blind study.

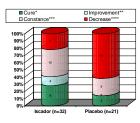
Subjects and Methods

53 horses with histologically confirmed diagnosis Equine Sarcoid were randomly assigned as Iscador (I; n=32) or Control group (C; n=21). There are 23 mares, 25 geldings and 5 stallions ranged in age from 3 to 17 years with an average of 7.2 years. The horses received escalating dosages of Iscador® P starting at 0.1mg up to 20 mg extract per 1 ml dose or physiological NaCl solution 3 times a week over 105 days sub-cutanously into the pectoral region. The number, localization and morphology of the ES were observed and documented over 12 months. As target variable the positive outcome rate (PO rate) was calculated representing the patients status at the end of the investigation.

Results

1. Tolerance and undesired side effects: As side effects of the Iscador® P injections in 5 of 32 cases a slight swelling (edema) could be observed which decreased spontanously within few days.

2. Overall outcome:

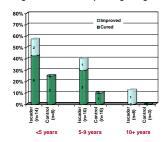


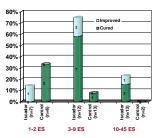


In the Iscador Group 13 horses (41%) showed an improvement (at least 50% tumour remission). Of these cases a number of 9 patients showed complete cure (28%). In the Control Group only 3 cases (14%; all with complete cure) were classified as improved (p<0.05).

or new tumours

Fig. 2b: outcomes depending on no. of ES Fig. 2a: outcomes depending on age





Younger horses responded more often with a positive outcome (PO) than older (Fig. 2a) with PO rates of 57%, 40% and 13% for horses being less than 5 years, 5 to 9 years and more than 9 years, respectively compared to PO 25%, 10% and 0% in control. A significant better therapy course appeared in the Iscador group for horses with >2 ES (Fig. 2b): a number of 12 of 25 horses (48%) showed an improvement, 9 of these a complete remission (36%) including ES localized at the critical areas (head and around the eyes) compared to 6% in the control group.

3. Cases

 Swiss Warmblood horse, mare. a. Swiss Warmblood horse, mare, aged 7 (1997)
Occult, verrucous und mixed sarcoids on head, neck, lower abdomen, and inner side of hind leg (n=7)
Iscador-treatment: 04-04 to 15-07-05

b. Franches-Montagnes horse aged 6 (1999)
Occult, verrucous and mixed sarcoid

head, lower abdomen and inner side of hind leg (n=9) Iscador-Treatment: 03-10-05 to 15-01-06

before therapy

month 1









Discussion & Conclusions

Iscador® P extract (viscum album pini) represents a safe and efficient therapy alternative in Equine Sarcoids, particularly in cases of multi-focal character. In tumours grown in problematic localizations a therapy attempt with viscum album extracts should be conducted to avoid the risk of damage the intact surrounding tissue, particularly in the eye area. Iscador® P shows significantly better outcomes (cure and improvement) compared to placebo control. Younger horses and horses with more than 2 tumours are responding with higher PO rates than older patients and horses with 1 to 2 ES. This fact could support the control of multiple sarcoids which can be excised only by immense surgery expense. Further investigations to understand factors of response and non-response have to be conducted in the future. Additionally, due to the good tolerance by the patients and the acceptance of long-term protocol the practicability of Iscador ® P therapy can be assumed.

Acknowledgements

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