Abstract: In a single-blind, randomized, bi-centric, prospective study, the non-inferiority of a fixed combination of thyme fluid extract and primrose root fluid extract (Bronchicum Elixir S, fluid test medication) was evaluated by comparison to a fixed combination of thyme fluid extract and primrose root tincture (Bronchicum Tropfen, drops test medication). The patients took either 6 x 5 ml of the fluid test medication (fluid group) or 5 x 1 ml of the drops test medication (drops group) daily. 189 outpatients (121 women, 68 men) suffering from acute, not previously treated bronchitis, lasting for less than 48 h, were randomized and treated with either fluid (94 patients: 66 women, 28 men) or drops (95 patients: 55 women, 40 men) over a time period of 7-9 days. 71 patients were excluded from the per-protocol (PP) collective because of violations regarding examination time points and/or intake of the study medication. The primary outcome criterion was to demonstrate the non-inferiority of the Score (BSS) at the end of the study compared to baseline. In the fluid group, the BSS decreased from 11.0 +/- 5.0 points at baseline to 2.6 +/- 4.6 (76%) at study end compared to a decrease from 11.0 +/- 4.8 points at baseline to 2.5 +/- 4.2 (77.1%) at study end in the drops group (Intention-to-treat (ITT) -analysis). The decrease of the BSS in
both groups was highly significant (p< or = 10(-3)), but there was no difference between the two
groups. Differences between the study sites were noticed regarding the baseline BSS, which were
twice as high at study site 2 compared to study site 1 (probably due to the different way the patients
were recruited). However, a statistically significant intergroup difference was not observed at any time
point. At the end of the study, 52.1% of the patients of the fluid group were symptom free and 53.7%
of the patients from the drops group were symptom free as compared by the ITT-analysis (secondary
outcome criterion). For both parameters, the PP-analysis support the non-inferiority of the fluid
compared to the drops. The global therapeutic efficacy of the fluid as well as of the drops was rated
as being "very good" or "good" by 80% of the patients and clinical investigators. The tolerability was
very good in both groups; neither serious adverse events nor clinically relevant findings in the safety
parameters were observed. A total of 10 adverse events occurred, 5 in the fluid group and 5 in the
drops group. Five of these adverse events (2 in the fluid group and 3 in the drops group) were
considered to be possibly or probably related to the intake of the study medication. Neither serious
nor unknown adverse drug reactions were observed. One drop-out occurred during the study,
because of ineffectiveness of the study medication. In the global safety assessment, the tolerability of
both medications was rated by about 90% of the patients and by clinical investigators as "good" or
"very good". The study demonstrated that the fixed combination of thyme fluid extract and primrose
root extract and the combination of thyme fluid extract and primrose root tincture were well tolerated
and showed comparable results regarding their efficacy, e.g. decrease of the bronchitis symptoms
(primary outcome criterion) and in relief of symptoms (secondary outcome criterion). The results of
the study confirm the non-inferiority of the fluid, a combination of thyme fluid extract and primrose root
effect when compared to the drops, a combination of thyme fluid extract and primrose root tincture.

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