Clinical Studies on Cat's Claw (*Uncaria guianensis* [Aubl.] Gmel.)

Anti-inflammatory

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Piscoya *et al.*, 2001	Safety and efficacy for osteoarthritis (knee)	P, R, DB, PC, PG, MC n=45 men (30=cat's claw; 15=placebo); with symptomatic osteoarthritis (OA) of knee, experiencing pain for most of prior month and requiring NSAID therapy for 3 months prior to study, with knee pain on movement (45–75 years)	4 weeks 7-day washout for NSAIDs; 12 hours for analgesics	One, 100 mg capsule/day	Freeze-dried cat's claw water extract; material made for study	UG group had significant improvement in pain associated with activity and patient assessment scores determined after 1 week of trial ($p<0.05$). Further, UG group showed highly significant improvement of these indices and medical assessment scores at weeks 2 and 4 ($p<0.001$). There was significant improvement in all 3 indices with treatment at week 4, compared to baseline and week 1 ($p<0.05$). However, pain at rest or at night, and knee circumference, were not significantly altered in either placebo or UG group, and there was no significant difference in side effects in either group and no adverse effects in blood or liver function were observed. Authors conclude based on human trial and in vitro component of study that UG and UT are safe and effective antioxidants, and UG and UT are equally bioactive for treatment of OA.

Clinical Studies on Cat's Claw (*Uncaria tomentosa* [Willd.] DC.)—focusing on preparations standardized to carboxy alkyl esters (CAEs)

Immunomodulation

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Lamm *et al.*, 2001	Immune system response to pneumonia vaccine	R, PC n=23 healthy caucasian males (40–60 years old)	2 months of treatment; evaluation at days 1, 30, 60, 180	700 mg/day (350 mg 2x/day) or placebo	C-Med-100® tablets (water soluble UT extract standardized to 8–10% CAEs)	UT group had elevated lymphocyte/neutrophil ratio at 2 months ($p<0.05$) and at 5 months showed no loss of immunity based on decay of 12 serotype pneumococcal antibody titers ($p<0.01$). Placebo group showed highly significant loss of immunity at 5 months. No toxic side effects were reported.
Sheng *et al.*, 2001	DNA repair, immune enhancement, and safety	R, PC n=12 healthy volunteers (mean age 44 years)	Baseline period of 3 weeks, then 8-week treatment	250 mg/day, or 350 mg/day, or placebo	C-Med-100® tablets	In both UT groups, there was 12–15% enhanced DNA repair (from 72–74% before treatment to 81–85% after treatment), as measured by alkaline elution, after 8 weeks of treatment ($p<0.05$). There was a tendency towards increased proliferation of phytohemagglutinin-induced lymphocyte proliferation, but results were not significant. No toxic responses were observed.
Sheng *et al.*, 2000a	Safety and immune enhancement	Volunteer supplement study n=4 apparently healthy adult males (32–58 years)	9 weeks Baseline then 6 weeks treatment	350 mg/day	C-Med-100® tablets	Subjects showed a significantly ($p<0.05$) increased level of white blood cells. No signs or symptoms of toxicity were observed.

KEY: C – controlled, **CAEs** – carboxy alkyl esters, **CC** – case-control, **CH** – cohort, **CI** – confidence interval, **Cm** – comparison, **CO** – crossover, **CS** - cross-sectional, **DB** – double-blind, **E** – epidemiological, **LC** – longitudinal cohort, **MA** – meta-analysis, **MC** – multi-center, **n** – number of patients, **O** – open, **OB** – observational, **OL** – open label, **OR** – odds ratio, **P** – prospective, **PB** – patient-blind, **PC** – placebo-controlled, **PG** – parallel group, **POAs** – pentacyclic oxindole alkaloids, **PS** – pilot study, **R** – randomized, **RC** – reference-controlled, **RCS** – retrospective cross-sectional, **RS** - retrospective, **S** – surveillance, **SB** – single-blind, **SC** – single-center, **TOAs** – tetracyclic oxindole alkaloids, **U** – uncontrolled, **UG** – *Uncaria guianensis*, **UP** – unpublished, **UT** – *Uncaria tomentosa*, **VC** – vehicle-controlled.

Clinical Studies on Cat's Claw (*Uncaria tomentosa* [Willd.] DC.)—focusing on preparations standardized to pentacyclic oxindole alkaloids (POAs) with no tetracyclic oxindole alkaloids (TOAs)

Anti-inflammatory

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Mur *et al*., 2002	Safety and efficacy in active rheumatoid arthritis (RA)	Phase 1: R, DB, PC Phase 2: all participants received cat's claw extract n=40 patients with active RA (Steinbrocker functional class II or III) (> or = 20 years of age)	52 weeks total with assessment at weeks 4, 8, 16, 24, 36, 52: Phase 1: 24 weeks Phase 2: 28 weeks	One capsule 3x/day (total 60 mg/day)	Krallendorn® capsules (20 mg cat's claw extract per capsule, containing 14.7 mg/g POAs and no TOAs)	At 24 weeks UT group compared to placebo showed reduced number of painful joints (by 53.2% vs. 24.1%; p=0.044). UT group experienced fewer tender joints (p=0.001) decrease in Ritchie Index (p=0.002) and shorter period of morning stiffness (p=0.002), whereas placebo group experienced no significant change. At 52 weeks UT-UT group showed further reduction in number of tender joints and in Ritchie Index, while placebo-UT group had a decrease in the number of painful and swollen joints (p=0.003; p=0.007) and decrease in Ritchie Index (p=0.004) compared to values at end of Phase I (placebo).
Immodal, 1995, 2002	Rhuematoid arthritis (RA), adjuvant to conventional treatment	C, UP n=6 patients (2 in Steinbrocker class I/II, 4 in Steinbrocker class II/III)	24 months of cat's claw treatment with assessment at months 3, 6, 12, 18, 24, and 8 years after completion of cat's claw treatment	Months 1–24: 60 mL tea/day (3 mg alkaloids/day) 4 patients continued treatment on their own after 2 years controlled phase: 1–3 capsules daily	Krallendorn® tea and capsules	At 3 months 3 patients had an increase in pain, while the other 3 had reduced pain. At 6 months all patients experienced reduced pain and joint stiffness. At 12 months 3 were largely pain-free, 3 had reduced pain with some pain-free periods, and dosages of conventional medications were reduced. At 18 months all patients were pain free. The 2 patients in class I/II remained symptom-free for 5–7 years after cat's claw treatment, while class II/III patients remained symptom-free for 1–2 years after cat's claw treatment. No adverse effects were reported.
Immodal, 1995, 1999a	Ulcers and gastritis	C, OB, UP Case reports n=7 patients with stomach or duodenal ulcers (n=5) or gastritis (n=2)	4 months. Months 1–3: cat's claw treatment Month 4 observation only	Decoction of 1.5 g in 120 ml water taken on empty stomach in morning	Krallendorn® tea	All 5 ulcer patients were asymptomatic after an average of 10 days and discontinued antacid treatment. Both patients with recurrent gastritis were asymptomatic after an average of 3 days and also stopped antacid treatment. All patients remained asymptomatic 1 month after discontinuation of cat's claw.

Immunomodulation

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Immodal, 1999a, 2002	Adjuvant to chemotherapy, radiation, and brain tumor resection	O, U, UP n=60	Varied: 12–31 months	60 mg/day	Krallendorn® drops	All patients reported greater vitality and fewer side effects from chemotherapy and radiation. Survival rates were not measurable since there were no controls.
Immodal, 1995, 2002	Adjuvant to chemotherapy, radiation, and surgery	U, UP n=22 patients with tumor diseases	12 months to 10 years	Tea: 60 ml/day Capsules: one capsule 1–3 x/day (20–60 mg/day)	Krallendorn® tea or Krallendorn® capsules	All patients showed increased vitality and fewer side effects. Partial remission in 5 patients, full remission in 13 patients, and prolonged survival time (>4 years in 7 patients). However, survival rates were not measurable, since there were no controls.
Immodal, 1995, 1999a, 2002	Adjuvant therapy for HIV patients	MC, O, U, UP n=44 patients in stages CDC A (n=16), CDC B (n=13), and CDC C (n=15)	12–60 months	1–6 capsules/day or equivalent amounts of drops or tea (20–120 mg/day capsules)	Krallendorn® capsules (n=41) or Drops (n=2) or Tea (n=1)	Cat's claw stabilized CD4-cell count in stage A patients and stabilized or increased it in stage B & C patients. A direct correlation was observed between CD4 cell count and total leukocyte and CD8 cell count. Symptoms decreased in stage B patients and disease progression was reduced in stage C patients. All patients experienced increased vitality and mobility. No adverse effects or drug interactions were observed.

KEY: C – controlled, **CAEs** – carboxy alkyl esters, **CC** – case-control, **CH** – cohort, **CI** – confidence interval, **Cm** – comparison, **CO** – crossover, **CS** - cross-sectional, **DB** – double-blind, **E** – epidemiological, **LC** – longitudinal cohort, **MA** – meta-analysis, **MC** – multi-center, **n** – number of patients, **O** – open, **OB** – observational, **OL** – open label, **OR** – odds ratio, **P** – prospective, **PB** – patient-blind, **PC** – placebo-controlled, **PG** – parallel group, **POAs** – pentacyclic oxindole alkaloids, **PS** – pilot study, **R** – randomized, **RC** – reference-controlled, **RCS** – retrospective cross-sectional, **RS** - retrospective, **S** – surveillance, **SB** – single-blind, **SC** – single-center, **TOAs** – tetracyclic oxindole alkaloids, **U** – uncontrolled, **UG** – *Uncaria guianensis*, **UP** – unpublished, **UT** – *Uncaria tomentosa*, **VC** – vehicle-controlled.

Clinical Studies on Cat's Claw (*Uncaria tomentosa* [Willd.] DC.)—focusing on preparations standardized to pentacyclic oxindole alkaloids (POAs) with no tetracyclic oxindole alkaloids (TOAs) (cont.)

Immunomodulation (cont.)

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Immodal, 1999a	Adjuvant therapy for HIV patients	O, U, UP n=14 patients with HIV or AIDS and a T4-cell count of 200–500 cells/mcL (6 also received AZT, 1 also received DDI)	1 year with assessments at months 0, 3, 6, 9, 12	2–3 capsules/day (40–60 mg/day)	Krallendorn® capsules	HIV-related symptoms were reduced. Slight increases were observed in heart beat, lymphocytes, uric acid, and in percent of T8 cells, as well as a decrease in granulocytes and a slight decrease in percent of T4 cells. Patients reported increased vitality.
Immodal, 1999a, 2002	Adjuvant therapy for HIV patients	RS, O, U, UP n=16 patients with HIV or AIDS	1–5.8 years	1–6 capsules/day (20–120 mg/day)	Krallendorn® capsules	Patients receiving antiretroviral therapy and cat's claw remained clinically stable and showed stable or increased CD4-cell counts. In those patients receiving cat's claw only, most remained clinically stable with stable CD4-cell counts. All patients reported increased vitality and mobility. No adverse effects or drug interactions were observed.

External Use

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Immodal, 1995, 1999a, 2002	*Herpes simplex*	O, MC, U, UP n=17	17 days	Once daily	Krallendorn® topical preparations of root extract: spray, ointment, cream, or gel containing 8 mcg POA/mg	Pain was eliminated in 14 patients by day 3 and in all 17 patients by day 7. Lesions had healed completely in 9 patients by day 7 and in all 17 patients by day 17. No adverse effects were observed.
Immodal, 1995, 1999a, 2002	*Varicella zoster*	O, U, UP n=20	13 days	Low dose group (n=16): once daily; High dose group (n=4): every 2 hours during waking hours	Krallendorn® topical preparations of root extract: spray, ointment, or cream containing 8 mcg POA/mg	Low dose group: 15 of 16 were symptom free by day 7 and lesions had healed for 15 of 16 by day 13. High dose group: all had greatly reduced pain on day 2 and all were pain-free by day 4. Scabs had disappeared by day 5. No adverse effects were observed.

KEY: C – controlled, **CAEs** – carboxy alkyl esters, **CC** – case-control, **CH** – cohort, **CI** – confidence interval, **Cm** – comparison, **CO** – crossover, **CS** - cross-sectional, **DB** – double-blind, **E** – epidemiological, **LC** – longitudinal cohort, **MA** – meta-analysis, **MC** – multi-center, **n** – number of patients, **O** – open, **OB** – observational, **OL** – open label, **OR** – odds ratio, **P** – prospective, **PB** – patient-blind, **PC** – placebo-controlled, **PG** – parallel group, **POAs** – pentacyclic oxindole alkaloids, **PS** – pilot study, **R** – randomized, **RC** – reference-controlled, **RCS** – retrospective cross-sectional, **RS** - retrospective, **S** – surveillance, **SB** – single-blind, **SC** – single-center, **TOAs** – tetracyclic oxindole alkaloids, **U** – uncontrolled, **UG** – *Uncaria guianensis*, **UP** – unpublished, **UT** – *Uncaria tomentosa*, **VC** – vehicle-controlled.