

# Theracurmin® Research & Clinical Trials

<http://theravalues.com/english/2015/10/20/research-clinical-trials/>

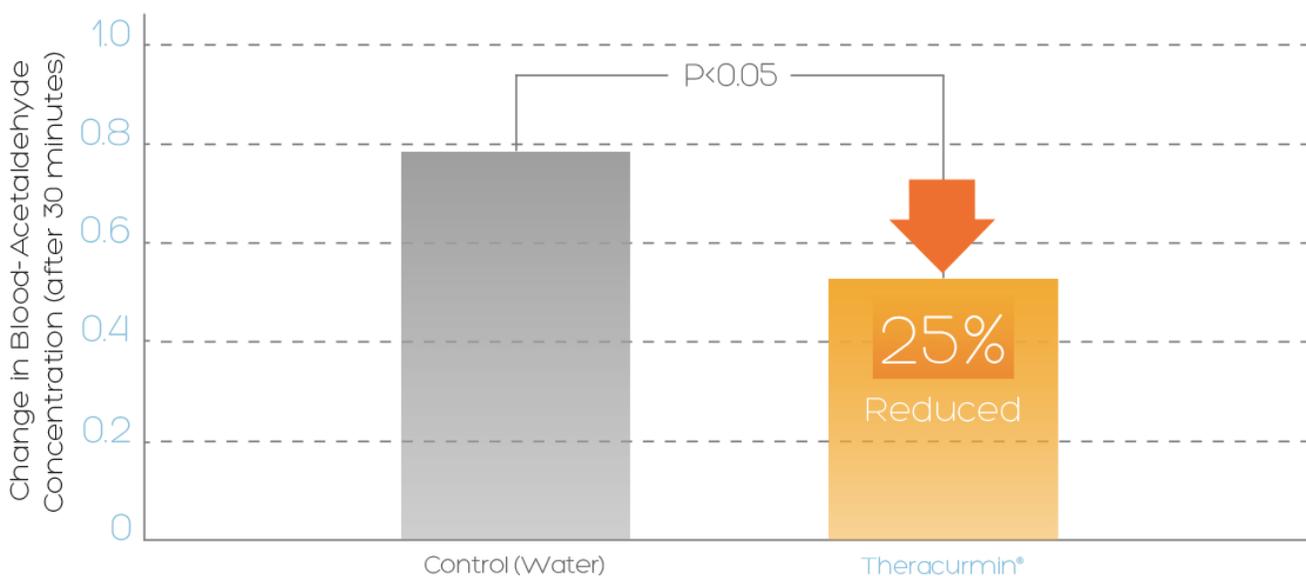
## Ongoing Clinical Trials

Research Area	Institute/University
Progressing malignancies	MD Anderson Cancer Center, University of Texas
NASH	Kyoto University Hospital
Mild cognitive impairment	UCLA
Heart failure / diastolic dysfunction: dose escalation trial	Kyoto Medical Center
Cachectic condition	Keio University
Schizophrenia	UCLA(VA Greater Los Angeles Healthcare System) Yale University
Osteoarthritis	Kyoto Medical Center
Crohn's disease	Hamamatsu Minami Hospital
Prostate-Specific Antigen after surgery	Teikyo University

## Detoxification / Alcohol Metabolism

Acetaldehyde is an alcohol metabolite and known as a cause of hangover. Recently it has been reported that acetaldehyde is strongly related to various diseases. In the human clinical trial, seven healthy volunteers participated by drinking the same amount of alcohol (.05mL ethanol/kg weight). After 30 minutes, those who consumed a follow-up Theracurmin® beverage containing 30 mg of curcumin lowered their blood-acetaldehyde concentration significantly (25%) when compared to those who drank water alone (control). The study confirmed that Theracurmin® has a positive effect on the alcohol metabolism in healthy volunteers.

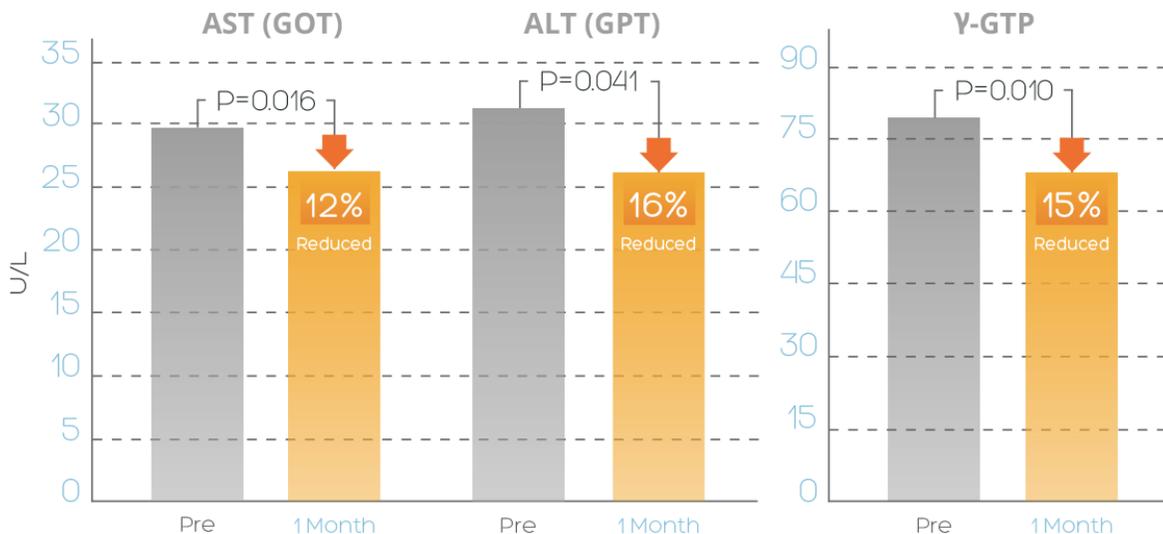
### Change in Blood-Acetaldehyde Concentration (after 30 minutes)



(Sasaki H., et al: Biol Pharm Bull.34(5):660-665, 2011)

## Detoxification / Liver Function

In another study, Theracurmin® was orally administrated to healthy volunteers, including those with relatively high values for liver function markers such as gamma-glutamyl transpeptidase ( $\gamma$ -GTP), aspartate transaminase (AST), and alanine transaminase (ALT), at a dose of 180 mg of curcumin daily for 1 month. Significant decreases were observed in AST (-12%), ALT (-16%), and  $\gamma$ -GTP (-15%). Further, liver function was more markedly improved in subjects who had higher baseline values than in those with relatively normal ones.



(Otsuka Y, et al: *The Journal of Japan Mibyou System Association* 16(2):331-333, 2010)

## Cancer

In this study, Theracurmin® was administered at a daily oral dose of 200mg or 400mg of curcumin along with Gemcitabine-based chemotherapy to 16 patients with refractory pancreatic or biliary tract cancer. The study documented their significantly improved quality of life scores by quantifying their experiences with fatigue, functional abilities, diarrhea, financial difficulties and appetite loss. 21% of the patients that ingested Theracurmin® during their treatment could survive more than one year.

### Changes in Quality of Life Scores

	Baseline	Best score during curcumin intake	Mean change	Value* <sup>3</sup>
Fatigue score	38.0 ± 13.2	24.8 ± 14.3	-13.2	0.004
Functional score* <sup>12</sup>	82.8 ± 11.9	90.7 ± 8.1	8.0	0.001
Diarrhea	15.0 ± 27.6	5.6 ± 12.4	-9.4	0.006
Financial difficulties	16.7 ± 25.5	2.8 ± 9.2	-13.9	0.027
Appetite loss	38.9 ± 26.6	22.2 ± 28.3	-16.7	0.026

\*1 - Five functional scores (emotional, role, cognitive, physical, and social functions) were pooled together

\*2 - A higher score indicates improved symptoms; otherwise, a lower score indicates improved symptoms

\*3 -  $P < 0.005$  was regarded as significant for multiple comparisons

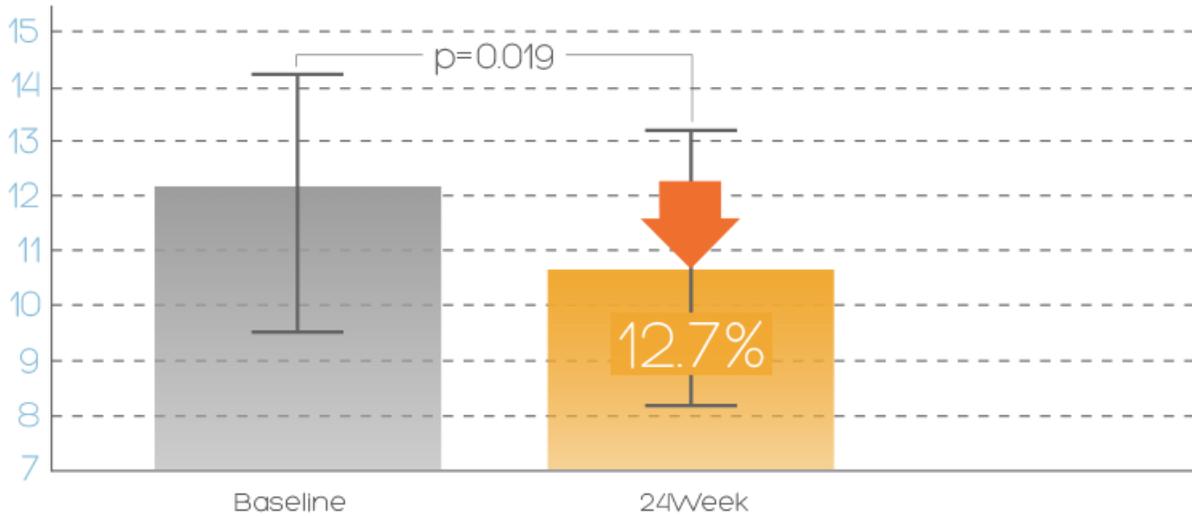
Kanai M, et al: *Cancer Chemother Pharmacol.* 30 March, 2013 (Published online)

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## Heart Failure

A double-blind clinical trial of 68 patients has shown that Theracurmin® can have positive effects on diastolic function in hypertensive patients with left ventricular hypertrophy. The patient group that ingested 60mg of curcumin a day for 24 weeks had a 12.7% reduction in LV stiffness (E/E') when compared to the patient group that ingested a placebo. Left ventricular diastolic failure was less severe in the heart hypertrophy patients that consumed the Theracurmin doses. This may lead toward treatment and prevention of diastolic heart failure.

### E/E'

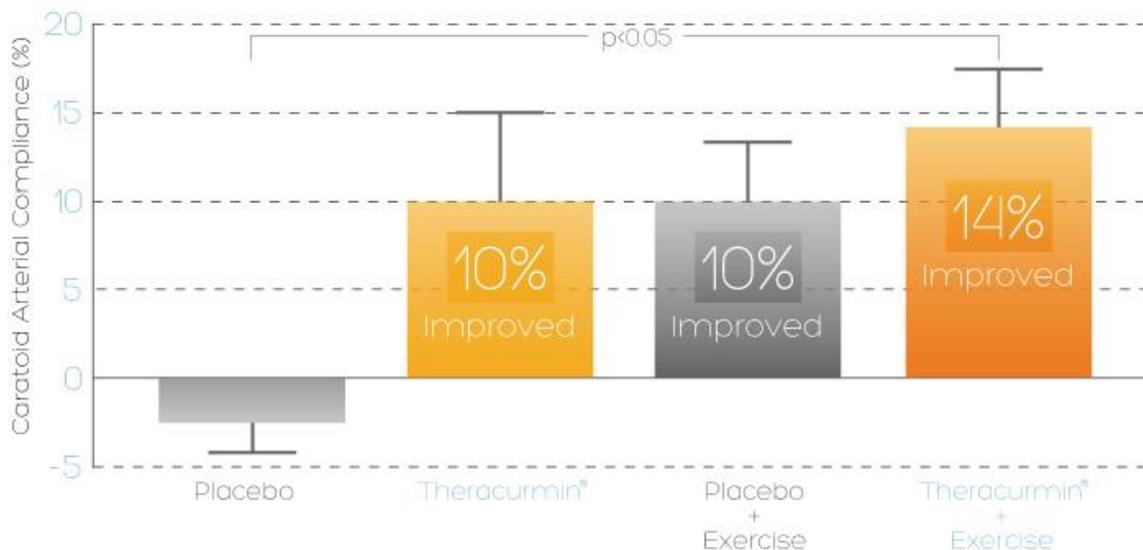


(American Heart Association, Nov.12-16, 2011 / American College of Cardiology, March 26, 2012)

## Arterial Stiffness

Multiple studies of double-blind clinical trials have been conducted to assess the effects of Theracurmin® on the arterial health of postmenopausal women. A combination of Theracurmin® ingestion (150mg of curcumin a day) and exercise training for 8 weeks was shown to significantly improve arterial compliance, vascular endothelial function and central arterial hemodynamics.

### Difference in Carotid Artery Compliance

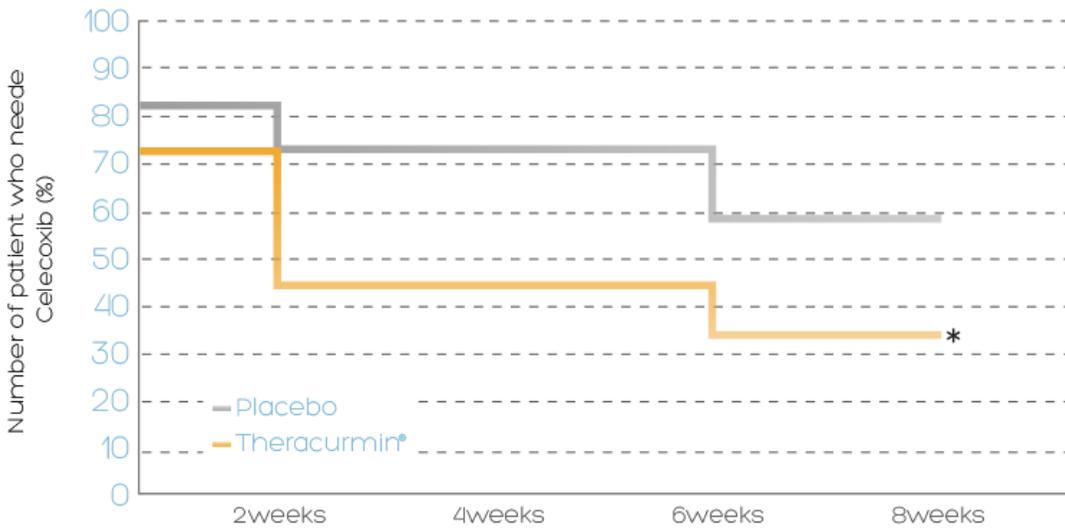


(Akazawa N., et al: Artery Research 7(1):67-72, 2013)

## Knee Osteoarthritis

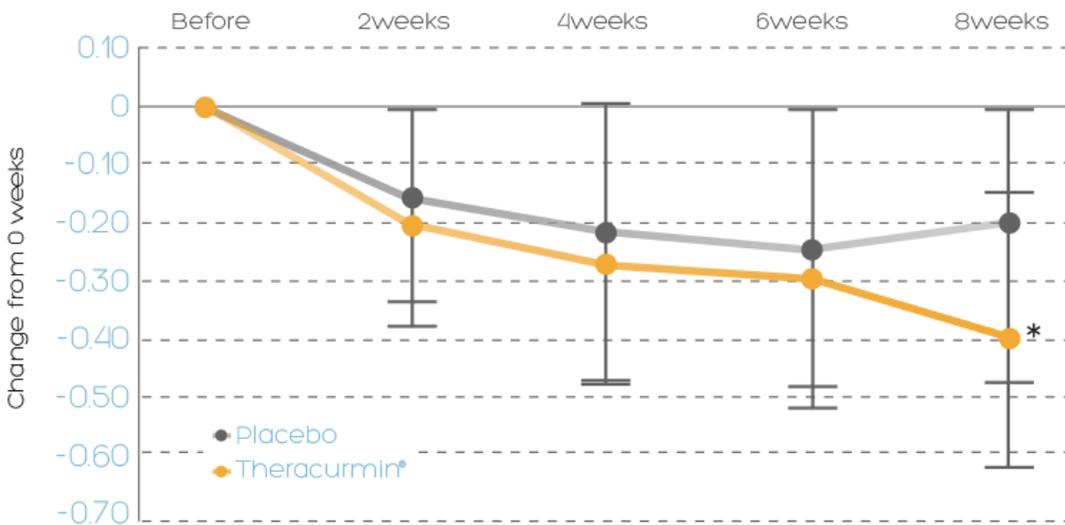
In a double-blinded, placebo-controlled, randomized, 8-week trial, 50 patients with medial knee osteoarthritis, aged 40 years or older, were divided into two groups of 25 people. The Theracurmin® group was given 180mg of curcumin a day and the results clearly indicated they experienced a significant reduction of knee pain when compared to the placebo group. In addition, the Theracurmin® group was able to reduce their dependence on NSAIDs to alleviate their pain.

### NSAID (Celecoxib) Dependence



\*p=0.0252 Theracurmin® vs Placebo, Chi square test

### VAS for Pain



\*p=0.023 Theracurmin® vs Placebo

(Nakagawa Y., et al: J Orthop Sci. Vol. 19, Nov. 6, 2014)