

Hydrazine Sulfate Human Studies Table

Return to [Summary of Research](#)

(Disease response and/or survival was the outcome assessed in all studies.)

*See legend below table for definitions of outcome codes.

Ref #	Sites	# Subj.	Stage	Patient Characteristics	Treatment	Outcome Assessed	Side Effects	Results
Randomized Clinical Trials								
⁸	Lung	119 cases 118 ctrls	III/IV (Adv.)	Unresectable, newly diagnosed, non small cell treated w/ cisplatin & etoposide	HS or placebo	Disease Response QOL		Times to regression: HS: 3.3 mo; Placebo: 4.2 mo (p=.04) Survival: HS: 5.8 mo Placebo.-8.0 mo
⁹	Colorectal	63 cases 64 ctrls	Mets		HS or placebo	Survival, quality of life, anorexia, weight loss		Poorer survival in HS group (p<.03). Poorer quality of life in HS group (p=.07). No significant differences in anorexia or weight loss.
¹⁰	Various	101	Adv.	Wt. loss >10% normal body wt. No severe renal or hepatic dysfunction. normal mental status pretreated	HS or placebo for 30 days	Wt. loss	Mild toxicity	Maintained/ increased weight: HS: 83% Placebo: 53% (p<0.05); Appetite improved: HS: 63% Placebo: 25% (p < 0.11).
¹¹	Lung	32 cases 33 placebo	Adv.	Unresectable non-small cell	HS or placebo for 30 days	Survival		Survival - All patients: HS: 292 days Placebo: 197 days (p<0.11) Survival – Best performance status at start of trial 328 vs 209 days (p<.05)
¹²	Lung	Six cases Six controls	Unspecified		60 mg HS; placebo three times daily for 30 days	Whole body protein breakdown		Plasma lysine: placebo grp. slight rise HS group sig. fall. Serum albumin: Placebo grp fell HS group no change.
¹³	Lung	135 cases 131 placebo	Locally Adv.	Non-small cell	Cisplatin, Vinblastin, with HS or placebo	Survival & tumor response	Major toxicity neutropenia	Survival: HS 7.78 mo Placebo 7.70 mo (p=.65) Tumor Response: HS: CR 4%, PR 20% Placebo CR 3%, PR 23% Sensory/motor neuropathy: HS: significantly worse Quality of life: HS: significantly worse

Hydrazine Sulfate Human Studies Table - continued

Ref #	Sites	# Subj.	Stage	Patient Characteristics	Treatment	Outcome Assessed	Side Effects	Results
Randomized Clinical Trials (continued)								
¹⁴	Various	19 cases 19 placebo	Mets	Wt. loss of \geq 10% body wt., normal liver function and mental status	60 mg HS or Placebo three times daily for 30 days	Carbohydrate metabolism	Minimal toxic effects	Glucose tolerance significant improvement HS (p<0.05)
¹⁵	Lung	72	Adv.	small cell	60 mg HS or placebo three times daily	glucose tolerance + glucose turnover + protein turnover	None	HS: All parameters improved (p<.05): Glucose toler. 69% vs 14% Glucose turnovr 71% vs 14% Protein turnover 83% vs 17%
Clinical Series								
¹⁶	Various	740	Adv. recur. or mets.	Failed surgery, radiation, or cytotoxic therapy	60 mg tablets of HS three times daily	Tumor resp.	Dizzy, nausea vomiting Excitement	CR: Six pts. (six mo-nine yrs); PR: 25 pts; no change-47 pts; interrupt tumor progression for >three months in 216 pts. Improved spirit
¹⁷	Brain	52	Recur	Six w/ benign tumors; 46 with cancer recurrence after surgery	60 mg tabs HS t.i.d. 30-40 days	Regr. Neuro symptoms/ survival		Malignant cases: 60.8% CR Any response 71.7% Incr. survival nine-16 mos. Improved quality of life
¹⁸	Various	25	Adv.	Progression following chemo	HS for 42 treatment days	Antitumor activity	Nausea	HS failed to demonstrate any benefit
¹⁹	Various	25	Adv		60 mg caps or placebo one to four times daily	Tumor Reduction	N/A	No pts had 5% reduction in tumor size. Brief subjective benefit in three patients
⁴	Various	32	Dissem.	Nonresectable	35 mg of HS	Tumor response		No sig antitumor response No sig subj. improvement
²⁰	Various	233	Dissem.		60 mg tablet or gelatin	Tumor response	Dizzy, vomit dyspepsia	42% anti-tumor effect 65% improved appetite, wt., reduced weakness, pain, fever.
²¹	Various	84	Dissem.	Terminal & pre-terminal	HS	Tumor response		17% improved objectively 70% improved subjectively
²²	Various	102	Adv.	Both sexes; previous surgery, radio, or chemo	HS oral 60 to 180 mg, two to three times daily; treatment varied from 1-5 mos	Antitumor and therapeutic effect; symptomatic action	Dizzy, excite, nausea, vomit, insomnia, and polyneuritic syndrome	No CR; 6 PR; Stabilized tumor growth for 1.5 to two months in 21%; therapeutic effect in 53.7% Improvement in patients' "dispositions"

Hydrazine Sulfate Human Studies Table - continued

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Clinical Series - continued								
²³	Various	10	Adv.		HS	Tumor response & subjective improvement	Gastritis, torpor, and weak	Two died, two unchanged, and six improved.
²⁴	Colon	22	Stage D	Biopsy proven nonresectable colon carcinoma	Series of three treatments of combined HS (60 mg) and 5-fluorouracil chemo	Metabolic effects of therapy	None reported	Decrease-plasma glucose, increase-triiodothyronine, serum transferrin - each p<0.025; no changes-insulin, IGF-1 glucagon, growth hormones, thyroxine, reverse triiodothyronine, cortisol, CEA "Survival time can be estimated with 59% accuracy using plasma LA, HGP, carcino-embryonic antigen, and insulin concentration."
Case Reports								
²⁵	Lung; CNS*	1	Adv.	63 years; female; terminal stage; completed radiation	HS; from one pill a day to three pills a day	Subjective improvement; therapeutic response	None reported	Demeanor, strength, and coherency improved dramatically; cough disappeared; patient could walk with assistance
²⁶	Femur and both lungs	1	Grade 1 (GCT)	27 years; female; femur GCT curetted; chemo produced no effect	60 mg to 120 mg of HS; three courses	Tumor response and benefit	None reported	Improvement in strength, well-being, and respiratory efficiency; weight gain; regression of chest disease and residual femur lesion.
²⁷	desmoid tumor of flank	1	Recurrent	Patient on glucose based total parenteral nutrition (TPN) due to bowel obstructions	60 - 180 mg HS with lipid based TPN & 40 mg oral glucose daily.	Tumor did not grow and slight decrease in one lesion.	None reported	Regimen tolerated well, no episodes of hypoglycemia.
⁶	Sq Cell Carc./ Esophagus	1		76 year old male	No conventional rx. 180 mg/day HS two weeks, then 360 mg/day for five weeks.	No effect on tumor	Neurotoxicity	Patient developed severe encephalopathy. HS was stopped and the condition was treated and reversed with Vitamin B ₆ .

Hydrazine Sulfate Human Studies Table - continued

Ref #	Sites	# Subj.	Stage	Patient Characteristics	Treatment	Outcome Assessed	Side Effects	Results
Case Reports - continued								
⁵	Sq. Cell Carc./ Maxillary sinus		None	55 year old male	No conventional rx. 180 mg/day HS for four months	No change in cancer symptoms	Death	Liver renal failure & death in spite of treatment with Vitamin B ₆ . Extensive laboratory studies unable to find any association other than the hydrazine sulfate.

*Central nervous system

*Legend

CODE	RESPONSE OR OUTCOME
CR	Complete Response
PR	Partial Response
SD	Stable Disease
DP	Disease Progression
OS	Objective Stabilization
OR	Objective Response
MR	Mixed Response
POS R	Positive Response
DT	Discontinued Treatment
U	Unknown
EXP	Expired
DR	Disease Response
S	Survival

Hydrazine Sulfate Reference List for Table of Human Research Studies

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[Back to the Top](#)