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WJH mainly publishes articles reporting research results and findings obtained in the field of hepatology and covering a wide range of topics including chronic cholestatic liver diseases, cirrhosis and its complications, clinical alcoholic liver disease, drug induced liver disease autoimmune, fatty liver disease, genetic and pediatric liver diseases, hepatocellular carcinoma, hepatic stellate cells and fibrosis, liver immunology, liver regeneration, hepatic surgery, liver transplantation, biliary tract pathophysiology, non-invasive markers of liver fibrosis, viral hepatitis.

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Anti-oxidative stress treatment and current clinical trials

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Abstract

Oxidative stress disturbs the balance between the production of reactive oxygen species (ROS) and the detoxification biological process. It plays an important role in the development and progression of many chronic diseases. Upon exposure to oxidative stress or the inducers of ROS, the cellular nucleus undergoes some biological processes *via* different signaling pathways, such as stress adaption through the forkhead box O signaling pathway, inflammatory response through the I κ B kinase/nuclear factor- κ B signaling pathway, hypoxic response *via* the hypoxia-inducible factor/prolyl hydroxylase domain proteins pathway, DNA repair or apoptosis through the p53 signaling pathway, and antioxidant response through the Kelch-like ECH-associated protein 1/nuclear factor E2-related factor 2 signaling pathway. These processes are involved in many diseases. Therefore, oxidative stress has gained more attraction as a targeting process for disease treatment. Meanwhile, anti-oxidative stress agents have been widely explored in pre-clinical trials. However, only limited clinical trials are performed to evaluate the efficacy of anti-oxidative stress agents or antioxidants in diseases. In this letter, we further discuss the current clinical trials related to anti-oxidative stress treatment in different diseases. More pre-clinical studies and clinical trials are expected to use anti-oxidative stress strategies as disease treatment or dietary supplementation to improve disease treatment outcomes.

Key Words: Anti-oxidative stress treatment; Clinical trials; Drugs; Dietary intervention; Reactive oxygen species

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Core Tip: Oxidative stress disturbs the balance between the production and detoxification of reactive oxygen species, which is implicated in many diseases. Therefore, anti-oxidative stress agents have been widely explored to treat chronic and metabolic diseases. In this letter, we further discuss the current clinical trials related to anti-oxidative stress treatment and summarize current medicines under investigation.

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TO THE EDITOR

With great interest, we read a recently published review paper authored by Li *et al*[1], discussing the progress of using herbal extracts from traditional Chinese medicine as a therapeutic method to treat liver fibrosis *via* inhibiting oxidative stress.

We agree with the authors that oxidative stress is a critical factor that can be targeted in the treatment of liver fibrosis. Oxidative stress is caused by an imbalance between the production and accumulation of reactive oxygen species (ROS) and the biological system to detoxify ROS products[2]. The accumulation of ROS can cause cell damage through the destruction of proteins and lipids, genetic modification, and disturbance of cellular signaling[2,3]. Therefore, oxidative stress has been recognized as a crucial factor involved in the underlying mechanisms of disease development and progression[4]. In fact, oxidative stress has gained more and more attraction recently due to its important roles in many diseases, such as heart disease[5], cancer[6], hypertension[7], cardiovascular diseases[8], aging[9], neurodegenerative disease[10,11], Alzheimer's disease[12], Parkinson's disease[13], and metabolic disorders. Moreover, oxidative stress also plays a pivotal role in organ transplantation[14] and infectious diseases[15]. Therefore, anti-oxidative stress as a therapeutic strategy has gained more attention for disease treatment.

Accumulating studies are performed to decipher the mechanism of oxidative stress in disease. Oxidative stress inducers include endogenous sources and exposomes[16]. Endogenous sources can induce the endoplasmic reticulum stress that may be caused by misfolded proteins, resulting in elevated levels of ROS[17]. The exposomes include but are not limited to toxins, irradiation exposure, air pollution, smoking, nutrients, chemicals, and infection[18]. Upon exposure to oxidant sources, the cellular nucleus undergoes several biological processes (Figure 1), such as stress adaption *via* the forkhead box signaling pathway[19], inflammatory responses through the nuclear factor (NF)- κ B and inhibitor of NF- κ B kinase signaling pathway[20,21], hypoxic responses controlled by hypoxia-inducible factor-1 α (HIF-1 α) and hypoxia-inducible factor-2 α (HIF-2 α) domain proteins[22], DNA repair or apoptosis process through the p53 signaling pathway[23], and antioxidant responses through the Kelch-like ECH-associated protein 1 (KEAP1)-transcription factor NF-E2 p45-related factor 2 (NRF2) (KEAP1-NRF2) signaling pathway[24]. The mitochondrion serves as an important organelle to generate ATP as an energy source, and ROS is also produced in this process. The accumulated excessive levels of ROS can result in oxidative stress[25]. Thus, the imbalance of the production of excessive oxidants and antioxidant processes leads to disease development and progression.

Inspired by this published review article, here, we give a further discussion on the current clinical trials that are related to anti-oxidative stress in different diseases using various intervention methods. Currently, two major categories including dietary supplement and drug treatment are used in clinical trials and summarized in this letter (Table 1). The most tested drug in these clinical trials is N-acetylcysteine with application in different diseases, such as cancer (melanoma and leukemia), pulmonary disease, renal disease, liver diseases such as non-alcoholic fatty liver disease, infectious diseases including severe acute respiratory syndrome coronavirus and human immunodeficiency virus infections, obesity, Parkinson's disease, and depressive disorders. The drug melatonin has also been used in many diseases, such as necrotizing enterocolitis, multiple sclerosis, and septic shock. Curcumin is a dietary supplement, which has been tested for renal transplantation disorder, coronary artery disease, metabolic syndrome, kidney disease, and others (Table 1). The data were collected from the website <https://clinicaltrials.gov> (accessed on October 28, 2023) using the keywords anti-oxidative stress, disease, and treatments such as drugs and nutrients, including ongoing and completed clinical trials.

In summary, oxidative stress is involved in many diseases and functions as a promising target in disease treatment and therapeutic drug screening. More potent antioxidants are expected to be explored to improve treatment outcomes. Meanwhile, the synergistic application of anti-oxidative drugs is an option to improve the therapeutic efficacy of other drugs.

Table 1 Clinical trials on anti-oxidative stress-related treatment

NCT number	Condition(s)	Category	Intervention(s)	Phase(s)
NCT05511766	Cirrhosis, hepatic encephalopathy	Drug	Allopurinol 300 mg, Atorvastatin 20 mg	2 and 3

NCT01054768	Anemia, sickle cell	Drug	Alpha-lipoic acid and acetyl-L-carnitine	2
NCT05558878	Diabetic peripheral neuropathy	Drug	Ambroxol oral product	NA
NCT00916448	Endotoxemia, multi-organ dysfunction	Drug	Atazanavir, <i>E. coli</i> endotoxin	NA
NCT03820245	Oxidative stress, atherosclerosis	Dietary	Bixin, norbixin, lycopene	NA
NCT05957432	<i>Helicobacter pylori</i> infection	Drug	Black seed oil, vonoprazan, amoxicillin, clarithromycin	2
NCT03529396	Vivax malaria, glucose-6-phosphate dehydrogenase	Drug	Chloroquine, primaquine	2
NCT03935958	Disorder in renal transplantation	Dietary	Curcumin	NA
NCT04458116	Coronary artery disease	Dietary	Curcumin	NA
NCT03514667	Metabolic syndrome	Dietary	Nanomicielle curcumin	NA
NCT04413266	Kidney diseases, peritoneal dialysis	Dietary	Curcumin supplementation	NA
NCT05966441	Chemotherapy peripheral neuropathy	Dietary	Curcumin, paclitaxel	2
NCT06083480	Osteoarthritis, knee arthroplasty	Drug	GlyNAC (combined glycine and N-acetylcysteine)	4
NCT01854294	Amyotrophic lateral sclerosis	Drug	GM604	2
NCT01891500	Persistent fetal circulation syndrome	Drug	Inhaled nitric oxide, nitrogen Gas	4
NCT05033639	Necrotizing enterocolitis	Drug	Melatonin 6 mg	1 and 2
NCT02463318	Multiple sclerosis	Drug	Melatonin, hydrogen peroxide	NA
NCT03557229	Septic shock	Drug	Melatonin, vitamins C and E, N-acetyl cysteine	3
NCT02587741	Diabetic retinopathy	Drug	Metformin, lantus, Novomix30	1
NCT01501929	Hypertension	Drug	Metoprolol succinate, nebivolol	4
NCT05742698	Frontotemporal dementia	Drug	Nabilone	2
NCT02294591	Bipolar disorder	Drug	N-acetyl cysteine	2
NCT02972398	Major depressive disorders	Drug	N-acetyl cysteine	NA
NCT01612221	Risk for melanoma	Drug	N-acetyl cysteine	2
NCT05611086	Lymphoblastic leukemia	Drug	N-acetyl cysteine	4
NCT01501110	Ischemic heart disease	Drug	N-acetyl cysteine	4
NCT05460858	Female infertility, endometrioma	Drug	N-acetyl cysteine	3
NCT03956888	Chronic obstructive pulmonary disease	Drug	N-acetyl cysteine	3
NCT01907061	Acute renal failure	Drug	N-acetyl cysteine	NA
NCT02124525	Tobacco smoking, inflammation	Drug	N-acetyl cysteine	3
NCT04792021	SARS-CoV-2 infection	Drug	N-acetyl cysteine	3
NCT04154982	Cardiac arrhythmia	Drug	N-acetyl cysteine	2
NCT03596125	Preterm delivery	Drug	N-acetyl cysteine	2 and 3
NCT04732000	Surgical recovery	Drug	N-acetyl cysteine	2
NCT02252341	Bipolar disorder	Dietary	N-acetyl cysteine	4
NCT01587001	Pulmonary sarcoidosis	Dietary	N-acetyl cysteine	NA
NCT01962961	HIV infection, endothelial dysfunction	Dietary	N-acetyl cysteine	1 and 2
NCT04440280	Fuchs endothelial corneal dystrophy	Drug	N-acetyl cysteine solution, visine	2
NCT02117700	Obesity, NAFLD, cardiovascular disease	Dietary	N-acetyl cysteine 600 mg	1 and 2
NCT05589584	Steatosis, non-fatty liver	Drug	N-acetyl cysteine	3
NCT04459052	Parkinson disease	Dietary	N-acetyl cysteine, F18 Fluorodopa	2
NCT01384591	Aging	Drug	N-acetyl cysteine, losartan	1 and 2
NCT03056014	Type 1 diabetes	Drug	N-acetyl cysteine, omega-6 fish oil	1
NCT04022161	Cardiovascular, endothelial dysfunction	Drug	Nitrogen gas for inhalation, nitric oxide	2

NCT03273413	Autosomal dominant polycystic kidney	Drug	Pravastatin	4
NCT02161653	Severe alcoholic hepatitis	Drug	Prednisone, metadoxine, pentoxifylline	4
NCT05770297	Endometriosis, dysmenorrhea	Dietary	Propolis	NA
NCT05753436	Diabetes, dyslipidemias, hypertension	Dietary	Puritans pride turmeric curcumin	2
NCT01663103	Renal insufficiency, chronic	Drug	Rilonacept	4
NCT01388478	Alzheimer's disease	Drug	R-pramipexole	2
NCT03738176	Oral lichen planus	Drug	Sesame oil, triamcinolone	1
NCT03402204	Ischemic stroke	Drug	Simvastatin 10 mg, simvastatin 40 mg	3
NCT05145270	Major depressive disorder	Dietary	Sulforaphane, escitalopram	4
NCT05149716	Oxidative stress	Dietary	Taurine	NA

NAFLD: Non-alcoholic fatty liver disease; NA: Not applicable.

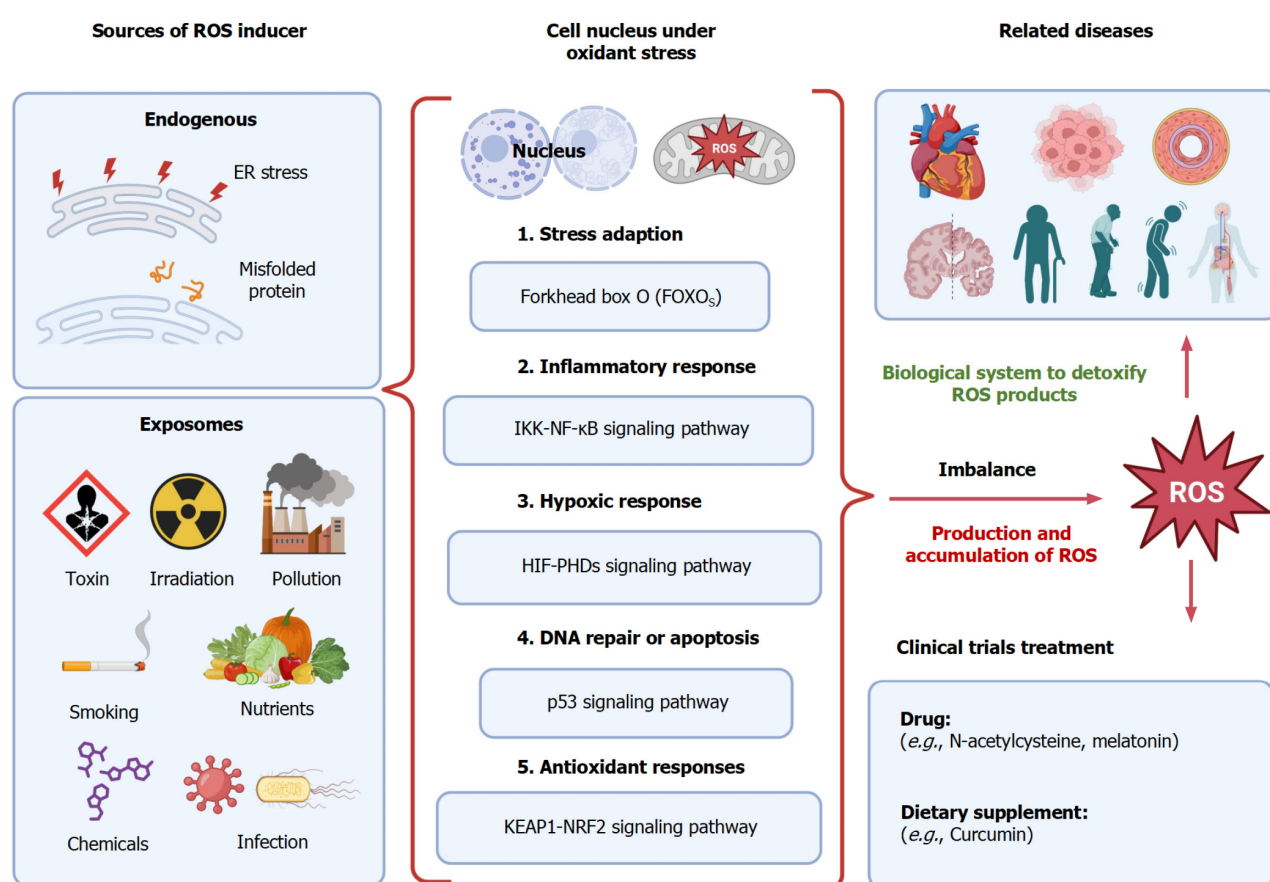


Figure 1 Diagram illustrating reactive oxygen species including inducers, mechanisms, related diseases, and clinical trial treatments. Inducers include endogenous and exposomes. The mechanism includes the cell nucleus response to exposure to reactive oxygen species (ROS) and the mitochondrial ROS response. The imbalance between the accumulation of ROS and their clearance by the biological system results in ROS-related diseases such as heart disease, cancer, hypertension, cardiovascular diseases, Alzheimer's disease, aging, neurodegenerative disease Parkinson's disease, and metabolic disorder. Current clinical trials mainly focus on the drug and dietary invention. ER stress: Endoplasmic reticulum stress; ROS: Reactive oxygen species; IKK-NF-κB: IκB kinase-nuclear factor-κB; HIF-PDHs: Hypoxia-inducible factor-prolyl hydroxylase domain proteins; p53: Tumor protein p53 or transformation-related protein 53; KEAP1-NRF2: Kelch-like ECH-associated protein 1-nuclear factor E2-related factor 2. All cartoons in this figure were prepared using Biorender (<https://biorender.com>, accessed on 7 January 2024).

FOOTNOTES

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