

Pharmacovigilance in Nanotechnology

PROF. ANAND SHUKLA Sims Anwar Pur Hapur UP

HOD Department of Pharmacology & Pharmacovigilance

Dr. Shambhavi Shukla Dental surgeon

Rishikesh UK

Dr. Madhu Shukla Registrar Cardiology

Fortis Hospital Shalimar Bagh, New Delhi

Abstract

Reducing size have different toxicological effect intrinsically. so safety evaluation of nanotechnology in surgical implants pose minimum risk but reaction surround tissues yet to be reported. Same thing Nan particle and nanostructure to be assessed. Regulatory point of view a risk management is already to be made in medical technology application. So competent authority and manufacturer must be aware to asses toxicological risk assessment.

Keywords: Nano toxicology, Nano particles, risk management medical technology ,nanotechnology, pharmacovigilance.

INTRODUCTION

Some Doctor worried about Nan drugs cross Blood Brain Barrier easily could damage human body and crossing placental and testicular border is not clear. Nanotechnology can make us smart and trans human in evolutionary path. And create two races one rich and second poor by making fast healing and Nano surgery with high cost. Now running electronic economy will change in Nano economy with nonscientist and Nano politicians, Nano physicians.

The use of nano medical application in diagnosis and imaging ,diseases, prosthesis and new drug delivery systems for harmful drugs are beneficial. But side by side Nan toxicology and adversity should be reported to regulatory authority for monitoring devices and drug early assessment and prevention for complications.

RISK MANAGEMENT:

The Nano toxicology should started immediately in medical products and medical devices for assessing risk by Nano particles in humans as well as animal experiments and in Hazards characterization as Epidemiological studies for workers, consumers, exposed population, in vivo studies for route of administration , acute, chronic in different species with in vitro studies in human/animal, different cell types Models lung, skin, systemic etc. Other studies may direct to biomaterials cellular growth, cell behaviors and influenced by nano chemical .

METHODS:

First find out exposure and uses for various route of exposure via dermal, parental, inhalation, ingestion, implantation, dermal. Recently Nano crystalline silver is as antibacterial may influence inflammatory response and cellular toxicity.

So biomaterials and implants have reactionary process differently than large molecules and tissue necrosis and healings should be assessed. In addition its inherent toxicity ,dosage uptake pharmacokinetics and pharmaco dynamics so physicochemical composition in Nano particle may have different effect over different biological compounds like endotoxines.

Seconds environmental exposure from free Nano particles and Nano tubes risk is related to occupational exposure for general population.

The over all adverse effect of nano sized air particles resultant effect in induction of oxidative stress in cells. Can damage cardiovascular, central nervous system and immune system.

DISCUSSION:

It was observed that Nano particles damage the epithelial tissues of lungs and effect over immunity on Ig E in animal model system of oval bumming allergy and induced toxicity in endothelial cells by induction of pro inflammatory cytokine IL8. carbon tube exposure cause oxidative stress and cellular toxicity for dermal tissues.

Mechanism of unwanted effects ADR by NANO DRUGS:

These all are Hypothesis:

- ⇒ Induction of oxidative stress by lipid per oxidation
- ⇒ Induction of cellular DNA damage
- ⇒ Increase induction of oxidative stress
- ⇒ Interaction with cells and tissues
- ⇒ Effects on immune system
- ⇒ Reduced function of macrophages and reduced phagocytosis of particles mobility and cytoskeleton dysfunction
- ⇒ Induction of pro inflammatory cytokines and mediators
- ⇒ Adverse effects on vascular homeostasis and osteoblasts
- ⇒ Nano particles are very reactive and endogenous proteins and cells can interact.

CONCLUSION:

WE here only discuss about only Nan drugs not all nanotech worlds as they also effect to human by inhalation. Observation with several chemicals show that nano chemicals are more toxic than large particles. So further ethics and assessments should be done before making it popular it can cause silent damage to death of Human

REFERENCES:

- Afaq F, Anodo P, Matin R, Rahman Q. Cytotoxicity, pro-oxidant effects and antioxidant depletion in rat lung alveolar macrophages exposed to ultrafine titanium dioxide. *J Appl Toxicol* 18, 307-312, 1998.
- Freitas, Jr., Robert A. "Nanotechnology, nanomedicine and nanosurgery. 'Lecture at Stanford University. September 12, 2006.
- <http://www.nanomedicine.com/Papers/Int1JSurgdec05.pdf>
- Alt V, Bechert T, Steinrucke P, Wagener M, Seidel P, Dingeldein E, Domann E, Schnettler R. An in vitro assessment of the antibacterial properties and cytotoxicity of nanoparticulate bone cement. *Biomaterials* 25, 4383-4391, 2004.
- Brook RD, Franklin B, Cascio W, Hong Y, Howard G, Lipsett M, Luepker R, Mittleman M, Samet J, Smith SC, Tager I. Air pollution and vascular disease. A statement for healthcare professionals from the expert panel on population and prevention science of the American Heart Association. *Circulation* 109, 2655-2671, 2004.